Clinical Development

Vedicinals-9

EPRD0202-010920 | CTRI/2020/10/028364

A randomized, open label, parallel efficacy, active control, multi-centre exploratory trial to evaluate efficacy and safety of vedicinals-9, an herbal formulation as adjunct treatment to standard of care for the management of mild to moderate covid-19 patients

Document type: Abbreviated Clinical Study Report

Development phase: II-b

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STUDY TITLE: A randomized, open label, parallel efficacy, active control, multi-centre exploratory trial to evaluate efficacy and safety of vedicinals-9, an herbal formulation as adjunct treatment to standard of care for the management of mild to moderate covid-19 patients.

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1 STUDY INFORMATION

Study title:

A randomized, open label, parallel efficacy, active control, multicentreexploratory trial to evaluate efficacy and safety of vedicinals-9, an herbalformulation as adjunct treatment to standard of care for the management of mildto moderate covid-19 patients.

Test investigational product: Vedicinals-9®

Indication studied: Novel coronavirus disease (COVID-19) [*Mild to moderate*]

Study design: See study title

Sponsor: Vedicinals India Pvt Ltd

Protocol identification:EPRD0202-010920

Development phase of study:II b

Study initiation date:11-Dec-2020 (first patient first visit)

Early termination date:NA

Study completion date:14-April-2021 (last patient last visit)

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Statement: This study was conducted in compliance with Good Clinical Practice (GCP), including the archiving of essential documents.

Report date(s):22-May-2021 (content final)

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2 SYNOPSIS

Name of Sponsor/Company: Vedicinals India Pvt Ltd	**Individual Study TableReferring to Partof the Dossier** **Volume:** **Page:**	**(For National Authority Use only)**
Name of Finished Product: Vedicinals-9		
Name(s) of Active Ingredient: Baicalin, Quercetin, Luteolin, Rutin, Hesperidin, Curcuminoids, Polyphenols, Piperine and Glycyerrhizin		

Title of Study:
A randomized, open label, parallel efficacy, active control, multi centre exploratory trial to evaluate efficacy and safety of vedicinals-9, an herbal formulation as adjunct treatment to standard of care for the management of mild to moderate covid-19 patients.

Investigators:
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Study centre(s):
Site 1: Aakash Healthcare Super Speciality Hospital, New Delhi, India
Site 2: Chirayu Medical College and Hospital, Bhopal, Madhya Pradesh, India

Publication (reference): NA

Studied period (years): 11-Dec-2020**(date of first enrolment)** 14-April-2021**(date of last completed)**	**Phase of development:** Nutraceutical Phase II-b

Objectives:
Primary Objective:
1.Percentage of COVID-19 patients & time taken to get COVID-19 RT-PCR negative 2.
Time of convalescence and improvement in altered biomarkers post COVID-19 infection
Secondary Objective:
1. Time to allaying a fever
2. Arrest or delay in progression in asymptomatic to mild or moderate to severe to critical 3.
Time to symptom relief
4. Days of treatment and Hospitalization
5. Incidence of respiratory failure and requirement of rescue medication 6.Percent
Mortality

Methodology:
A total of 124 adults with SARS-COV2 like symptoms and confirmed COVID-19 positive report were recruited for the trial. The patients were randomly assigned into the following two groups; Standard care group (*CLINICAL MANAGEMENT PROTOCOL: COVID-19, Government of India, Ministry of Health and Family Welfare, Directorate General of Health Services, EMR Division, Version 4, 27.06.20*) (n=62) and adjuvant treatment (Vedicinals-9) group add on to standard treatment 5000 mg per day in 50ml suspension (n=62). The enrolment and allocation procedures were as per randomization schedule. Patients consumed either standard treatment alone or in combination with vedicinals-9 for 14 consecutive days at a dose of 5000 mg per day TID daily. The patients in adjuvant treatment (Vedicinals-9) received loading dose on day 1 of 25 ml each at 1 hour before breakfast, lunch and dinner. On subsequent days, the patients received the maintenance dose of 20 ml, 15 ml and 15 ml at 1 hour before breakfast, lunch and dinner respectively. At Day 0, 5±2 and 12±2 of ingestion, the postingestion test and patient symptom were assessed along with other haematological, biochemical and biomarkers tests. A follow-up visit of 30 days was conducted after the end of treatment period and haematological, biochemical and biomarker tests will be conducted on day 45±2. All data were recorded in the Case

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Report Form (CRF). All essential documents of this clinical study (ICF, CRFs, source documents i.e. questionnaires, lab reports, scans, etc.) were archived.
Number of patients (planned and analysed): 124 planned (n=62 each arm); Analysed 124 for treatment period (14 days) and 119 for follow up period
Diagnosis and main criteria for inclusion: 1.Individuals of either sex above 18 and below 60 years of age 2.Individuals who have been tested positive to be infected with SARS-COV2 Virus and presenting with no symptoms or mild to moderate symptoms. 3.Voluntariness to participate in the trial and give signed informed consent.
Test product, dose and mode of administration, batch number: Vedicinals-9, 5000 mg per day in 50ml suspension orally TID in divided doses of 20 ml, 15 ml and 15 ml for 14 days, batch number S/SCL/20001, S/SCL/20002 and S/SCL/20003.
Duration of treatment: 14 days (2 Weeks)
Reference therapy, dose and mode of administration, batch number: As per appendix 16.1.6 Listing of standard medicinal product(s)

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Criteria for evaluation:

Efficacy:

The primary efficacy endpoint in this study was the percentage of patients getting COVID-19 RT-PCR negative and time taken to get the same from days from admission, days from first testing positive, days from first noticed symptoms. The other primary efficacy endpoint in this study was the change from baseline (CFB) to day5, 12 and 45 in CRP, Total Antibody, IL-6 and change from baseline (CFB) to day12 and 45 in Ferritin, D-dimer, Troponin 1, CD4+ T cell, CD8+ T cell, CD19+ B cell, CD16+ CD56+ NK cell. CFB in biomarkers = improvement in altered biomarkers post COVID-19 infection. The primary analysis set for the efficacy analysis was the FAS.Analyses of treatment differences of secondary endpoints was planned to use the same methods as those for the primary endpoint. Hypothesis tests were to use the same null and alternative hypotheses with μ representing the mean for the variable being tested.

Safety

The planned safety analyses consisted of descriptive summaries of the data as relevant to the scale of data, e.g., frequency and percent for adverse events, and mean changes from baseline as appropriate. Frequency and percentage of patients were provided for each categorical variable by treatment group.Safety assessments consisted of collecting all adverse events (AEs), serious adverse events (SAEs), with their severity and relationship to study drug. Safety evaluation included vital signs (blood pressure, SpO2, pulse and respiratory rate), physical examination, haematological, biochemical, urinalysis and pregnancy test (for women of child bearing potential).

SUMMARY – CONCLUSIONS

EFFICACY RESULTS:

A total of 124 patients mean age 40.71±1.55 (IQR 40.50; 18-60) in standard group and 38.82±1.35 (IQR 39; 18-60) in vedicinals-9 with standard group having 56.45% (35) male, 53.22% (33) female and 43.55% (27) male, 46.78% (29) female respectively were included in the study.

The percentage of COVID-19 positive patient's (RT-PCR) turning negative in 0-4, 5-11, 12-14 days were 29.03%, 48.39% and remaining 22.58% respectively in Vedicainals-9 adjuvant group compared to the standard treatment alone group 1.61%, 37.10% and remaining 61.29% respectively. The results show more patients getting negative in first 5 days in Vedicainals-9 adjuvant group compared to standard alone group.

The mean number of COVID-19 patients at risk (staying positive) from day 0 to 14 is significantly low (7.62±0.45, **P<0.01) in Vedicainals-9 adjuvant group compared to the standard treatment alone group (9.71±0.45).

The improvement (*Increase*) in mean CT value (Viral Load) of COVID-19 positive patients from day 0 to 5 was significant (1.762±0.125, *P<0.05) in Vedicainals-9 adjuvant group compared to the standard treatment alone (1.399±0.092).

Among 124 patients included in the study; 17.7% (22/124) of cases had prolonged fever, and 15.3% (19/124) had saddleback fever. Out of which 6.4% (08/124) of cases had prolonged fever, and 4.8% (06/142) had saddleback fever in standard group; 11.2% (14/124) of cases had prolonged fever, and 10.5% (13/124) had saddleback fever in vedicinals-9 adjuvant group. The mean time in days for allaying prolong fever (<7; 5±2 days) from first testing positive, onset and admission (*treatment*) were 7.12, 6.12, 4.12 days in standard group compared to 5.14, 5.42 and 3.60 days in vedicinals-9 adjuvant group. Similarly, the mean time in days for allaying saddleback fever (>7; 12±2 days) were 13.16, 14.00, 11.83 days in

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standard group compared to 13.38, 13.53 and 11.53 days in vedicinals-9 adjuvant group. *The Vedicinals-9 adjuvant group had a mean duration of fever of 3.5 days compared to 4.12 days for prolonged fever cases, while fever recurred at a mean of 11.53 days compared to 11.83 days for those with saddleback fever cases.*

Among 124 patients included in the study; 13.70% (17/124) of cases had cough, and 20.96% (26/124) had saddleback cough. Out of which 3.22% (04/124) of cases had cough, and 11.29% (14/124) had saddleback cough in standard group; 10.48% (13/124) of cases had cough, and 9.67% (12/124) had saddleback cough in vedicinals-9 adjuvant group. The mean time in days for allaying cough (<7; 5±2 days) from first testing positive, onset and admission (*treatment*) were 6.50, 5.25, 5.25 days in standard group compared to 5.69, 4.53 and 4.53 days in vedicinals-9 adjuvant group. Similarly, the mean time in days for allaying saddleback cough (>7; 12±2 days) were 12.79, 11.57, 11.57 days in standard group compared to 13.17, 11.33 and 11.33 days in vedicinals-9 adjuvant group. *The Vedicinals-9 adjuvant group had a mean duration of allaying cough of 4.53 days compared to 5.25 days for cough cases, while cough recurred at a mean of 11.33 days compared to 11.57 days for those with saddleback cough cases. Both cough and saddleback cough were likely to be associated with disease progression and pneumonia.*

Among 124 patients included in the study; 08.87% (11/124) of cases had fatigue, and 18.54% (23/124) had prolonged fatigue. Out of which 2.42% (03/124) of cases had fatigue, and 10.48% (13/124) had prolonged fatigue in standard group; 07.25% (9/124) of cases had fatigue, and 08.06% (10/124) had prolonged fatigue in vedicinals-9 adjuvant group. The mean time in days for allaying fatigue (<7; 5±2 days) from first testing positive, onset and admission (*treatment*) were 9.33, 5.00, 5.00 days in standard group compared to 5.78, 4.44 and 4.44 days in vedicinals-9 adjuvant group. Similarly, the mean time in days for allaying prolonged fatigue (>7; 12±2 and 45±2 days) were 36.50, 41.13, 42.13 days in standard group compared to 25.40, 26.44 and 26.00 days in vedicinals-9 adjuvant group. *The Vedicinals-9 adjuvant group had a mean duration of allaying fatigue of 4.44 days compared to 5.00 days for fatigue cases, while prolonged fatigue at a mean of 26.44 days compared to 42.13 days for those with prolonged fatigue cases. Both fatigue and prolonged fatigue were likely to be associated with disease progression.*

Among 124 patients included in the study; 17.74% (22/124) of cases had myalgia, and 12.90% (16/124) had prolonged myalgia. Out of which 5.64% (07/124) of cases had myalgia, and 09.67% (12/124) had prolonged myalgia in standard group; 12.09% (15/124) of cases had myalgia, and 3.22% (4/124) had prolonged myalgia in vedicinals-9 adjuvant group. The mean time in days for allaying myalgia (<12; 12±2 days) from first testing positive, onset and admission (*treatment*) were 11.14, 9.57, 10.29 days in standard group compared to 9.00, 6.53 and 7.26 days in vedicinals-9 adjuvant group. Similarly, the mean time in days for allaying prolonged myalgia (>12; 12±2 days) were 47.67, 45.25, 45.25 days in standard group compared to 45.25, 44.75 and 44.75 days in vedicinals-9 adjuvant group. *The Vedicinals-9 adjuvant group had a mean duration of allaying myalgia of 7.26 days compared to 10.29 days for myalgia cases, while prolonged myalgia at a mean of 44.75 days compared to 45.25 days for those with prolonged myalgia cases. Both myalgia and prolonged myalgia were likely to be associated with disease progression.*

Among 124 patients included in the study; 22.58% (28/124) of cases had sore throat, and 4.03% (5/124) had prolonged sore throat. Out of which 12.09% (15/124) of cases had sore throat, and 2.41% (03/124) had prolonged sore throat in standard group; 10.48% (13/124) of cases sore throat, and 1.61% (02/124) had prolonged sore throat in vedicinals-9 adjuvant group. The mean time in days for allaying sore throat (<12; 12±2 days) from first testing positive, onset and admission (*treatment*) were 11.47, 10.40, 10.40 days in standard group compared to 8.15, 7.23 and 7.23 days in vedicinals-9 adjuvant group. Similarly, the mean time in days for allaying prolonged sore throat (>12; 12±2 days) were 45.00, 44.67, 44.67 days in standard group compared to 10.33, 8.33 and 8.33 days in vedicinals-9 adjuvant group. *The Vedicinals-9 adjuvant group had a mean duration of allaying* sore throat *of 7.23 days compared to 10.40 days for* sore throat *cases, while* prolonged sore throat *at a mean of 08.33 days compared to 44.67 days for those with* prolonged sore throat *cases. Both* sore throat *and* prolonged sore throat *were likely to be associated with disease progression.*

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Among 124 patients included in the study; 20.16% (25/124) of cases had mild-moderate hypoxia, and 20.16% (25/124) had severe hypoxia (SpO_2<90). Out of which 13.70% (17/124) of cases had mildmoderate hypoxia (SpO_2<90), and 14.51% (18/124) had severe hypoxia (SpO_2<90) in standard group; 6.45% (8/124) of cases had mild-moderate hypoxia, and 5.64% (7/124) had severe hypoxia (SpO_2<90) in vedicinals-9 adjuvant group. The mean time in days for allaying mild-moderate hypoxia (SpO_2>90-94) from first testing positive, onset and admission (*treatment*) were 6.94, 7.64, 6.58 days in standard group compared to 4.75, 5.50 and 2.57 days in vedicinals-9 adjuvant group. Similarly, the mean time in days for allaying severe hypoxia (SpO_2<90) were 6.77, 7.50, 6.44 days in standard group compared to 6.14, 7.00 and 6.00 days in vedicinals-9 adjuvant group. *The Vedicinals-9 adjuvant group had a mean duration of allaying* mild-moderate hypoxia (SpO_2>90-94) *of 2.57 days compared to 6.58 days for mild to moderate hypoxia cases, while* severe hypoxia (SpO_2<90) *at a mean of 6.00 days compared to 6.44 days for those with prolonged fatigue cases. Both mild-moderate and severe hypoxia were likely to be associated with disease progression and admission to ICU.*

The mean time in days to remain hospitalized with subsequent discharge was 4 to 6.5 days for 37.09% (23/62) of COVID-19 patients in standard group compared to 58.06% (36/62) days in vedicinals-9 adjuvant group. Similarly, the mean time in days for 43.54% (27/62) of COVID-19 patients in standard group compared to 29.03% (18/62) days in vedicinals-9 adjuvant group was 7 to 12 days. Those with mean time in days <12 days were 19.35% (12/62) in standard group compared to 12.90% (08/62) in vedicinals-9 adjuvant group. *The Vedicinals-9 adjuvant group had more than 58 % patients discharged from hospital in first 4 to 7 days of testing positive compared to the 37 % standard treatment group.*

No incidence of respiratory failure and rescues medication observed in entire trial duration (*Observation and Follow up period*). No mortality observed in entire trial duration (*Observation and Follow up period*)

*The improvement (decrease) in mean serum CRP levels (mg/L) of COVID-19 positive patients from day 0 to 5, 12 and 45 was significant (10.29±1.44 to 6.93±0.47, ***P<0.001), (5.04±0.32, ***P<0.001) and (3.33±0.18, ***P<0.001) in Vedicainals-9 adjuvant group compared to the standard treatment alone (12.04±0.87 to 9.23±0.49, **P<0.01), (5.15±0.32, ***P<0.001) and (3.54±0.18, ***P<0.001).*

*The improvement (Increase) in mean serum Ferritin levels (µg/L) of COVID-19 positive patients having iron deficiency from day 0 to 12 and 45 was significant (12.71±2.09 to 47.24±22.12 and 67.83±16.35, *p<0.5 and **p<0.01) in Vedicainals-9 adjuvant group compared to the standard treatment alone (14.57±2.18 to 36.02±13.02 and 62.13±09.45, p>0.5 (ns) and *p<0.05).*

*The improvement (decrease) in mean serum Ferritin levels (µg/L) of COVID-19 positive patients having excess iron from day 0 to 12 and 45 was significant (558±52.71 to 262.6±46.11 and 152.0±18.14, ***p<0.001 and ***p<0.001) in Vedicainals-9 adjuvant group compared to the standard treatment alone (541.5±40.89 to 295.7±11.68 and 142.8±15.04, ***p<0.001 and ***p<0.001).*

*The improvement (Increase) in mean serum Ferritin levels (µg/L) of COVID-19 positive patients having normal iron from day 0 to 12 and 45 was significant (91.29±12.67 to 94.50±13.77 and 162.7±13.56, p>0.05 (ns) and ***p<0.001) in Vedicainals-9 adjuvant group compared to the standard treatment alone (50.10±06.87 to 56.57±4.32 and 192.9±14.40, p>0.05 (ns) and ***p<0.001).*

*The improvement (Increase) in mean serum Total antibody levels (g/L) of COVID-19 positive patients from day 0 to 5, 12 and 45 was significant (2.61±0.42 to 5.02±0.47, 5.97±0.46 and 13.64±1.44, *p<0.05, *p<0.05 **p<0.01)in Vedicainals-9 adjuvant group compared to the standard treatment alone (1.92±0.37 to 3.64±0.72, 3.63±0.27 and 11.23±1.15, p>0.05(ns), p>0.05(ns) and **p<0.01).*

*The improvement (decrease) in mean serum IL-6 levels (pg/mL) of COVID-19 positive patients from day 0 to 5, 12 and 45 was significant (12.79±5.35 to 4.01±0.36, 3.62±0.39 and 2.70±0.24, *p<0.05, *p<0.05 **p<0.01)in Vedicainals-9 adjuvant group compared to the standard treatment alone (12.48±4.53 to 5.91±1.53, 6.18±1.83 and 2.98±0.68, p>0.05(ns), p>0.05(ns) and **p<0.01).*

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The improvement (decrease) in mean serum D-Dimer levels (µg FEU/L) of COVID-19 positive patients from day 0 to 12 and 45 was significant (416.7±43.45 to 351.8±28.48 and 261.5±14.15, p>0.05 (ns) and

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****p<0.001) in Vedicainals-9 adjuvant group compared to the standard treatment alone (410.8±45.67 to 687.7±187.2 and 285.4±12.34, p>0.05 (ns) and p>0.05 (ns).*

*The improvement (decrease) in serum CPK levels (U/L) of COVID-19 positive patients from day 0 to 5, 12 and 45 was significant (109.1±21.65 to 96.84±16.84, 76.57±5.34 and 124.1±5.7, p>0.05 (ns), **p<0.01)in Vedicainals-9 adjuvant group compared to significant (increase) in standard treatment alone (78.45±5.35 to 71.63±3.78, 68.91±4.73 and 131.5±5.3, p>0.05(ns), p>0.05(ns) and *p<0.05).*

*The improvement (Increase) in mean serum CD4+ levels (cells/µL) of COVID-19 positive patients from day 0 to 12 and 45 was significant (957.6±69.24 to 1201±94.19 and 1289±115.2, **p<0.01 and **p<0.01) in Vedicainals-9 adjuvant group compared to the standard treatment alone (1190±67.65 to 1607±107.9 and 1655±117.5, *p<0.05 and *p<0.05).*

*The improvement (Increase) in mean serum CD8+ levels (cells/µL) of COVID-19 positive patients from day 0 to 12 and 45 was significant (797±65.43 to 1094±105.2 and 1113±103.5, *p<0.05 and *p<0.05) in Vedicainals-9 adjuvant group compared to the standard treatment alone (1002±68.70 to 1329±105.5 and 1370±117.5, *p<0.05 and *p<0.05).*

The improvement (Increase) in mean serum CD19+ levels (cells/µL) of COVID-19 positive patients from day 0 to 12 and 45 was non-significant (240.6±19.55 to 270.8±20.88 and 242.5±21.09, p>0.05 (ns) and p>0.05 (ns) in Vedicainals-9 adjuvant group compared to the standard treatment alone (263.5±28.30 to 241.3±19.06 and 194.8±15.83, p>0.05 (ns) and p>0.05 (ns).

The improvement (Increase) in mean serum CD16+/56+ NK levels (cells/µL) of COVID-19 positive patients from day 0 to 12 and 45 was non-significant (205.1±17.73 to 246.8±21.72 and 219.7±19.51, p>0.05 (ns) and p>0.05 (ns) in Vedicainals-9 adjuvant group compared to the standard treatment alone (205.1±17.73 to 216.5±22.61 and 179.6±18.09, p>0.05 (ns) and p>0.05 (ns).

SAFETY RESULTS:

There were no deaths or SAEs reported during the study. One non-serious event (Headache) was reported by the one patient who was randomized to standard. The event of headache was mild in severity and was not related to the study medication. There were no AEs leading to discontinuation reported during the study.

CONCLUSION:

This retrospective study demonstrates a potential promising role of Vedicinals-9 as adjuvant therapy on the evolution of symptomatology, strengthen the natural defences to COVID-19 patients and in post COVID-19 secondary complication. Specially for the symptoms fever, dry cough, dyspnoea, headache, diarrhoea and weakness, reduction of viral load and the recovery time for the treated patients was significant shorter in comparison to the standard treatment. In addition, post COVID-19 secondary complication like Cardiovascular, Neurological, Pulmonary, Renal, Myocardial, Hepatic and Pancreatic were attenuated in the adjuvant treated patients in comparison to the standard treatment alone. A controlled, double-blind, randomized clinical trial in a larger population (Phase III) is therefore currently being recommended.

Date of the report: May 20, 2021

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4 LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

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ADM	Analysis Da
ADR	Adverse Dru
AE	Adverse Eve
ALP	Alkaline ph
ALT	Alanine tra
AST	Aspartate a
BP	Blood Press
CBC	Complete B
CFB	Change fror
COVID-19	Coronavirus
CoVs	Corona Viru
CPK	Creatine Ph
CRF	Case Report
CRO	Contract Re Organizatio
CRP	C-Reactive
EC	Ethics Com
EDTA	Ethylene di acetic acid
EOS	End of Stud
ESR	Erythrocyte Rate
FAS	Full Analys
FBS	Fasting Blo
g	relative cen
GCP	Good Clinic
HDL	High-densit
ICF	Informed C
ICH	Internation Harmonizat
ICMR	Indian Med Research
IEC	Institutiona Ethics Com
IgG	Immunoglol
IgM	Immunoglol
IL-6	Interleukin-
INR	Internation Ratio
IP	Investigatio
IRB	Institutiona
LAR	Legally Acc Representat
LD50	Lethal Dose
LDL	Low-density lipoprotein
LFT	Liver Function Tests
LMWH	Low Molecular Weight Heparin
MedDRA	Medical Dictionary for Regulatory Activities
min	minimum
mITT	Modified Intent-to-Treat
mL	millilitre
N	Blood Urea Nitrogen
NK	Natural Killer Cells
NOAEL	No-observed-adverse-effect level
PP	Per-Protocol Population
PPS	Per Protocol analysis set
PT	Prothrombin Time
QA	Quality Assurance
RBC	Red Blood Count
RFT	Renal Function Tests
RT-PCR	Real Time Polymerase Chain reaction
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SAS	Statistical Analysis Software
SD	Standard Deviation
SDTM	Study Data Tabulation Model
SOPs	Standard Operating Procedures
SpO2	Oxygen Saturation Pulse
SST	Serum Separator Tube
TC	Total Cholesterol
TEAE	Treatment Emergent Adverse Event
TG	Triglycerides
UFH	Unfractionated Heparin
UPT	Urine Pregnancy Test
VLDL	Very low-density lipoprotein
WBC	White Blood Count
WHO	World Health Organization
WHO-UMC	World Health Organization - Uppsala Monitoring Centre

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5 ETHICS

5.1 Institutional/Independent ethics committee

The study protocol and all amendments were reviewed by the Institutional/Independent Ethics Committee (IEC) for each centre, as listed in Appendix 16.1.1.

5.2 Ethical conduct of the study

The study was conducted according to the ethical principles of the Declaration of Helsinki (52nd WMA General Assembly, Edinburgh, Scotland, October 2000) and in agreement with the International Conference on Harmonisation (ICH) guidelines on Good Clinical Practise (GCP).

5.3 Patient information and consent

Informed consent was obtained from each patient in writing at the screening visit. The patient information sheet detailed the procedures involved in the study (aims, methodology, potential risks, anticipated benefits) and the investigator/designee/CRC explained these to each patient. The patient signed the consent form to indicate that the information had been explained and understood. The patient was then allowed time to consider the information presented before signing and dating the informed consent form to indicate that they fully understood the information, and willingly volunteered to participate in the study. The patient was given a copy of the informed consent form for their information. The original copy of the informed consent was kept in a confidential file in the Investigators centres records.

Samples of the written information given to each patient and the consent form are presented in Appendix 16.1.3.

5.4 CTRI Registration

This trial is registered and approved with the clinical trials registry – India with the following number CTRI/2020/10/028364 on 12/10/2020. A copy can be found in Appendix 16.1.9.

6 INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

The administrative structure of the study, including internal and external participants, is described in Appendix 16.1.4.

A list of Investigators, their affiliations and their qualifications, plus that of other important staff is provided in Appendix16.1.4.

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Ethix Pharma's clinical research team analyzed this study and authored this report. The signatures of the Principal and Coordinating Investigator, the Sponsor's Responsible Medical Officer, and the report authors are provided in Appendix 16.1.5.

7 INTRODUCTION

7.1 Background

Coronaviruses are large group of viruses that cause illness in humans and animals. Rarely, animal coronaviruses can evolve and infect people and then spread between people such as has been seen with MERS and SARS. The outbreak of Novel coronavirus disease (COVID-19) was initially noticed in a seafood market in Wuhan city in Hubei Province of China in mid-December, 2019, has now spread to 214 countries / territories /areas worldwide. WHO (under International Health Regulations)has declared this outbreak as a "Public Health Emergency of International Concern" (PHEIC) on 30th January 2020. WHO subsequently declared COVID-19 a pandemic on 11th March, 2020.

Current available evidence for COVID-19 suggests that the causative virus (SARS-CoV-2) has a zoonotic source closely related to bat-origin SARS-like coronavirus. It is an enveloped RNA beta coronavirus related to the Severe Acute Respiratory Syndrome (SARS) virus, and the virus has been shown to use the angiotensin-converting enzyme 2 (ACE2) receptor for cell entry. The persons infected by the novel coronavirus are the main source of infection. Direct personto-person transmission occurs through close contact, mainly through respiratory droplets that are released when the infected person coughs, sneezes, or talks. These droplets may also land on surfaces, where the virus remains viable. Infection can also occur if a person touches an infected surface and then touches his or her eyes, nose, or mouth.

The median incubation period is 5.1 days (range 2–14 days). The precise interval during which an individual with COVID-19 is infectious is uncertain. As per the current evidence, the period of infectivity starts 2 days prior to onset of symptoms and lasts up to 8 days. The extent and role played by pre-clinical/ asymptomatic infections in transmission still remain under investigation. Most patients with COVID-19 predominantly have a respiratory tract infection associated with SARS-CoV-2 infection. However, in a small proportion of cases, they can progress to a more severe and systemic disease characterized by the Acute Respiratory Distress Syndrome (ARDS), sepsis and septic shock, multiorgan failure, including acute kidney injury and cardiac injury. Autopsy findings in China and European countries showed endothelial damage of pulmonary vasculature, microvascular thrombosis and haemorrhage linked to extensive alveolar and interstitial inflammation that ultimately result in COVID-19 vasculopathy, pulmonary intravascular coagulopathy, hypercoagulability, ventilation perfusion mismatch,

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and refractory ARDS. Hypoxemia, secondary to ARDS may also activate the coagulation cascade.

Infection prevention control (IPC) along with symptomatic management are often preferred as initial line of treatment for mild to moderate cases. In mild COVID-19 cases symptomatic treatment such as antipyretic (Paracetamol) for fever and pain, adequate nutrition and appropriate rehydration is advised. Patients with suspected or confirmed moderate COVID-19 (pneumonia) had to be isolated to contain virus transmission.These patient must undergo detailed clinical history including co-morbid conditions, measurement of vital signs, Oxygen saturation (SpO2) and radiological examination of Chest X-ray,
Complete Blood Count and other investigations as indicated. Clinical Management of Moderate cases includes Oxygen Support, monitoring of CRP, Ddimer & Ferritin every 48-72 hourly (if available); CBC with differential count, Absolute Lymphocyte count, KFT/LFT daily along with symptomatic treatment with Tab. Hydroxychloroquine (400mg) BD on 1st day followed by 200mg 1 BD for 4 days (after ECG Assessment), methylprednisolone 0.5 to 1 mg/kg OR Dexamethasone 0.1 to 0.2 mg/kg for 3 days (preferably within 48 hours of admission or if oxygen requirement is increasing and if inflammatory markers are increased) to be considered. Review for duration of administration as per clinical response is required. If required Anticoagulation Prophylactic dose of UFH or LMWH (e.g., enoxaparin 40 mg per day SC) is suggested. Control of comorbid condition, monitoring for Increased work of breathing (use of accessary muscles), Hemodynamic instability, Increase in oxygen requirement and secondary bacterial infection is advised. Empiric antibiotic therapy as per local antibiogram and guidelines is suggested. Close monitoring of patients with moderate COVID-19 is required for signs or symptoms of disease progression. (*CLINICAL MANAGEMENT PROTOCOL: COVID-19, Government of India, Ministry of Health and Family Welfare, Directorate General of Health Services, EMR Division, Version 4, 27.06.20*)

Despite the efficacy of the above clinical management protocol, a significant proportion of patients require more than one medication to reach target outcome. Clinicians must often add medications or switch to more powerful combination of treatment in order to reach targeted relief in disease progression and manage the signs or symptoms, after initiation of a specific standard treatment regime. The Nine Active Phyto-Compounds; 5000 mg per day in 50 ml suspension i.e. 100 mg/ml formulation is marketed under the trade name of Vedicinals-9®. In this present study, Vedicinals-9, dosed thrice daily (TID), has been shown to enhance the anti-viral, anti-inflammatory, immuno-modulatory and anti-coagulation properties of standard treatment as an adjunctive therapy from baseline. The mechanism by which Vedicinals-9 enhances the efficacy differs from existing monotherapies and thus Vedicinals-9 may be a suitable adjunctive therapy for patients on standard treatment that require further attenuation in disease progression. Hence, the combination of standard treatment + Vedicinals-9 should be evaluated to understand the best possible clinical management regime further.

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7.2 Purpose

The purpose of this study was to determine the incremental lowering of disease progression in mild to moderate COVID-19 cases that is achieved when Vedicinal-9, TID, is used adjunctively to standard treatment for clinical management in patients with altered pathophysiology that may benefit from further lowering of disease progression. Data from this study was intended for publications and to provide health care practitioners with important treatment guidance on the use of Vedicinals-[1] in this clinical setting.

The study was completed on 14-April-2021successfully as per protocol adhering to GCP without any safety concerns (see further details in Section 9.4.9). All participating sites were promptly notified for completing the enrolment and study specific visits.

8 STUDY OBJECTIVES

8.1 Primary objective and related endpoint

Primary objective	End Point for Primary Objective
1. Percentage of COVID-19 patients & time taken to get COVID-19 RT-PCR negative	Days from admission, days from first testing positive, days from first noticed symptoms.
2. Time of convalescence and improvement in altered biomarkers post COVID-19 infection	Change from baseline to end of the study

8.2 Secondary objective and related endpoint

Secondary objective	End Point for Secondary Objective
1. Time to allaying a fever	Days from admission, first testing positive and first noticed symptoms.
2. Arrest or delay in progression in to mild or moderate to severe to critical	Days from admission, first testing asymptomatic positive and first noticed symptoms.
3. Time to symptom relief	Days from admission, first testing positive and first noticed symptoms.

[1] **INVESTIGATIONAL PLAN**

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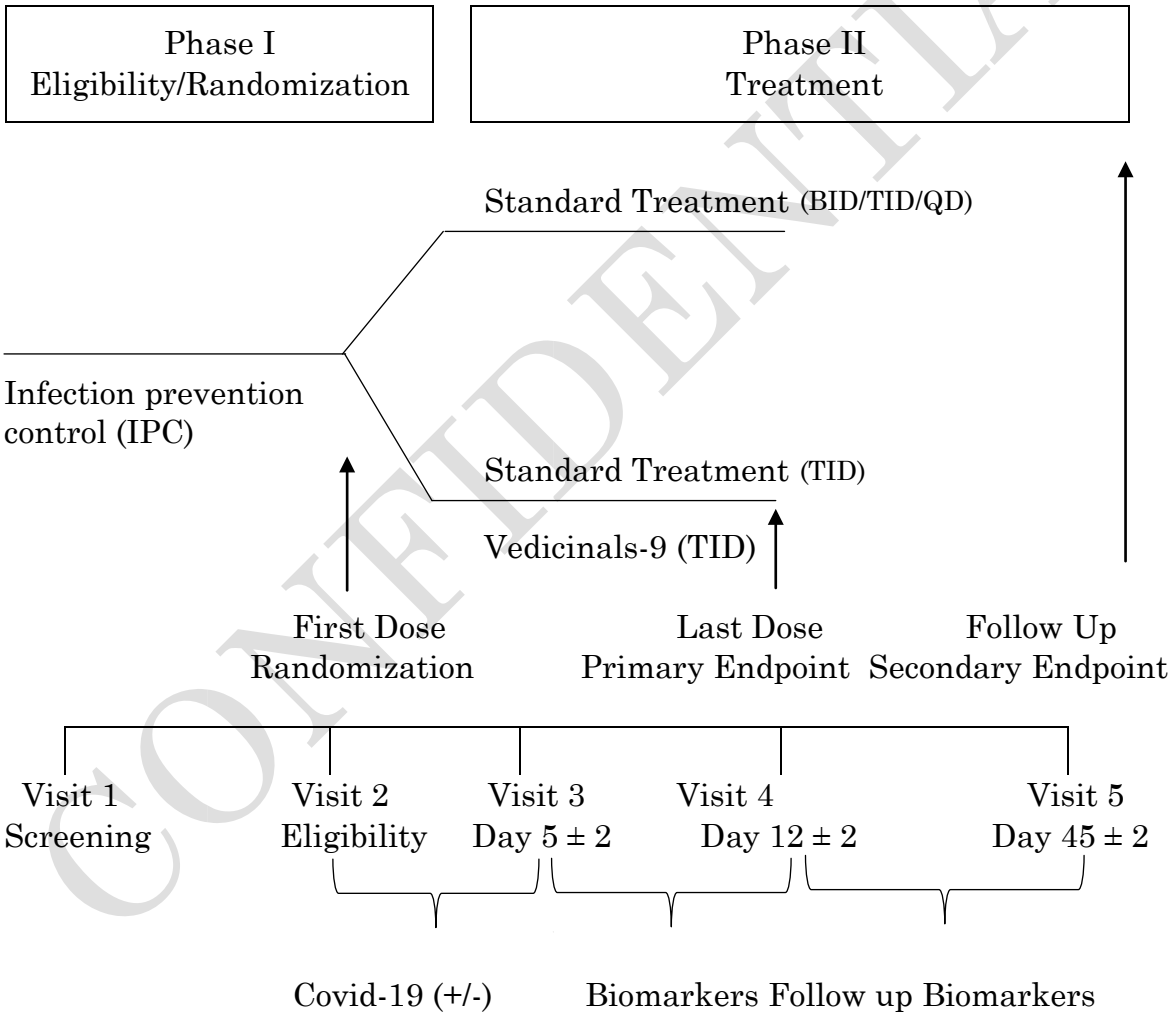
4. Days of treatment and discharged — Throughout the study period until Hospitalization

5. Incidence of respiratory failure of rescue medication — Throughout the study period and requirement

6. Percent Mortality — End of the study

9.1 STUDY DESIGN

Figure 9.1 Study Design



BID: twice a day, TID: Thrice a day, QD: once a day.

This was a multi-center, randomized, open label, parallel efficacy, active control, exploratory study in mild to moderate covid-19 patients who were controlled on standard treatment regime. A total of 124 patients were planned to be randomized

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and treated for up to 2 weeks followed by a 30 day follow up post treatment. The study was divided into 2 sequential phases for a total of 5 visits:

Phase I: Screening/Eligibility phase
Phase II: Treatment Phase

For full details of study design refer to Appendix 16.1.1-Protocol-Section 5

9.2 DISCUSSION OF STUDY DESIGN, INCLUDING THE CHOICE OF CONTROL GROUPS

Despite the efficacy of the standard clinical management protocol, a significant proportion of patients require more than one medication to reach target outcome of symptomatic relief. This study was designed to investigate the incrementalattenuation in disease progression that is achieved when Vedicinals9 is added to standard treatment which is often used as initial therapy to manage mild to moderate covid-19 cases. Understanding the magnitude of further lowering in disease progression that could be achieved by the addition of Vedicinals-9 to standard in a low baseline setting, could only be achieved with a standard comparator and could provide essential data to health care practitioners.

The study was designed to minimize the study length and assessments, while ensuring scientific validity: the eligibility visit was to minimize regression to the mean and increase the likelihood of stable baseline entry data; the Day 12 ± 2 visit allowed patient safety to be monitored during the treatment phase; the primary assessments were at 12 ± 2 days to minimize patient time in the trial. Assessments at day 45 allowed to evaluate the prolonged effect of vedicinals-9 in adjunct with standard care in comparison to standard treatment alone.

Selection bias was reduced by randomization.

9.3 POPULATION

The study population consisted of adult and elderly patients 18 years of age or older, with confirmed SARS-COV2 Virus (Covid-19), RT-PCR tested positive report and presenting with no symptoms or mild to moderate symptoms.

9.3.1 Inclusion criteria

Key inclusion criteria

1. Individuals of either sex above 18 and below 60 years of age
2. Individuals who have been tested positive to be infected with SARS-COV2 Virus and presenting with no symptoms or mild to moderate symptoms.
3. Voluntariness to participate in the trial and give signed informed consent.

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Inclusion criteria are described in details in Appendix 16.1.1-Protocol-Section 6.4

9.3.2 Exclusion criteria

Key exclusion criteria

1. COVID-19 Patients with symptoms classified as severe or critical
2. Individuals with uncontrolled, unstable comorbidities as evaluated by the investigators.
3. Individuals with pre-existing respiratory conditions, severe primary respiratory disease or pneumonia.
4. Immuno-compromised Individuals or those on immunosuppressant
5. Patients on or requiring parenteral nutrition/care.
6. Pregnant/lactating women.
7. COVID-19 positive individuals participating in the interventional arm of other COVID-19 clinical trial.
8. Individuals with serious complications of diseases such as cancer, heart disease, infraction, stroke, arterial fibrillation, cardiac arrhythmia, disabilities, neurodegenerative disease.
9. Subjects with alcohol and/or substance dependence.
10. Subjects with known allergic reactions to any other herbal supplements.

Exclusion criteria are described in details in Appendix 16.1.1-Protocol-Section 6.4

9.4 TREATMENT

9.4.1 Treatment administered (Investigational and control treatment)

Vedicinals-9® (The nine active phyto-compounds; 5000 mg per of nine active phyto-compounds in 50 ml suspension i.e. 100 mg/ml) suspension was supplied in opaque bottle with a label indicating that the product is for investigational use only. All standard treatment medicine used by the site was in its commercial form available in market and was unmasked (open label) product (Refer Appendix 16.1.6). All test materials were supplied by Vedicinals India Pvt Ltd. The batch and formulation numbers of Vedicinals-9is provided in Table 9-1 and the details are mentioned in Appendix 16.1.11.

Table 9-1 Study medication formulation and batch numbers

Study drug and strength	Batch number
Vedicinals-9® (5000 mg of nine active phyto-compounds in 50 ml suspension i.e. 100 mg/ml)	S/SCL/20001, S/SCL/20002, S/SCL/20003

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9.4.2 Identity of Investigational Product(s) (Treatment arms)

Patients were assigned at Visit 2 (Eligibility) to one of the following two treatment arms in a ratio of 1:1

- Arm 1: Standard Treatment (dosed in the morning and in the evening)
- Arm 2: Standard Treatment + Vedicinals-9 (dosed in the morning, afternoon and in the evening)

9.4.3 Treatment assignment and randomization

Refer to Appendix 16.1.1-Protocol-Section 5.4 for details of randomization procedures.

The randomization scheme for patients was reviewed and approved by a member of the Ethix Pharma Office. The randomization list is provided in Appendix 16.1.7.

9.4.4 Treatment dose selection (Treatment masking)

Patients, investigator staff, persons performing the assessments, and data analysts remained masked to the identity of the treatment from the time of randomization until database lock, using the following method: (1) Randomization data were kept strictly confidential until the time of unmasking, and were not accessible by anyone else involved in the study

9.4.5 Dosing the patient and timing

9.4.5.1 Patient numbering

Each patient was uniquely identified in the study by a combination of his/her centre number and a 2-digit Patient Number.

9.4.5.2 Dispensing the study treatment

Each study site was supplied with study drug (Vedicinals-9) in packaging of identical appearance labelled with the protocol and kit numbers. The study drug was dispensed as described in Appendix 16.1.1-Protocol-Section 7.4 and 7.5.

9.4.5.3 Supply, storage and tracking of study treatment

For details on handling of study treatment, refer toAppendix 16.1.1-ProtocolSection 7.6.

9.4.5.4 Instructions for prescribing and taking study treatment

General instructions:

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- Patients had to take Vedicinals-9 in three divided doses 1hr before meal as advised.
- Patients had to shake study medication before use.
- Patients were not allowed to discard any unused or empty bottles and bring all study medication bottles to the study visit.

Appendix 16.1.1-Protocol-Section 5.5 describes the detailed instructions for Vedicinals-9 administration during treatment phase.

All kits of investigational treatment assigned by the lab is as per their approved protocol and were recorded in their QMS for accreditation system.

The investigator promoted compliance by instructing the patient to apply the study drug exactly as prescribed and by stating that compliance is necessary for the patient's safety and the validity of the study. The patient was instructed to contact the investigator if he/she was unable for any reason to apply the study drug as prescribed.

9.4.5.5 Permitted dose adjustments and interruptions of study treatment
Study drug dose adjustments and/or interruptions were not permitted.

9.4.5.6 Rescue medication

Rescue medication were permitted as per standard care of management in this study. If an Investigator felt a patient was not adequately controlled on study medications, they were discontinued from receiving the study treatment and were managed accordingly to usual care.

9.4.6 Blinding

Not applicable

9.4.7Prior and Concomitant treatment

The Investigator instructed the patient to notify the study site about any new medications he/she took after the start of the study drug.

All medications and significant non-drug therapies (including physical therapy and blood transfusions) administered after the patient was enrolled into the study was recorded on the Concomitant medications log and after start of study drug in Case Report Form (CRF).

9.4.8 Discontinuation of study treatment and premature patient withdrawal

Patients could voluntarily withdraw from the study for any reason at any time. A patient could be considered withdrawn if he or she stated an intention to

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withdraw, failed to return for visits, or became lost to follow-up for any other reason.

The Investigator was obliged to discontinue study drug for a given patient or withdraw the patient from the study if, on balance, he/she believed that continuation would be detrimental to the patient's well-being.

Refer to Appendix 16.1.1-Protocol-Section 6.5 for details on discontinuation of studytreatment and withdrawal of informed consent, and Appendix 16.1.1Protocol-Section 6.5.1for criteria for referral of patient to modern medical care facility

9.4.9 Emergency unmasking of treatment assignment

Not applicable

9.4.10 Early study termination

According to Appendix 16.1.1-Protocol-Section 15.3, the study could be terminated by Vedicinals India Pvt Ltd at any time for any reason. This could include reasons related to the benefit risk assessment of participating in the study, practical reasons, or for regulatory or medical reasons (including slow enrolment). If this was necessary, the patient was to be seen as soon as possible and treated as a prematurely withdrawn patient. The Investigator could be informed of additional procedures to be followed in order to ensure that adequate consideration was given to the protection of the patient's interests. The Investigator was responsible for informing the Institutional Review Board/Independent Ethics Committee (IRBs/IECs) of the early termination of the study.

This study was not terminated early due to none of the above reasons or any safety concerns.

The present study was completed successfully and reported accordingly.

9.4.11 Treatment exposure and compliance

All study treatment dispensed and returned were recorded in the Drug Accountability Log.

Refer to Appendix 16.1.1-Protocol-Section 7.7 for further details

9.5 EFFICACY AND SAFETY ASSESSMENTS

9.5.1 Visit schedule

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The study visits and procedures are presented in Appendix 16.1.1-Protocol Section 5.2-Table 1which lists all of the assessments and indicates with an"✓" the visits at which they were performed.

All activities performed during eligibility visits E1 (Visit 1) and E2 (Visit 2), during week 1 (Visit 3), week 2 (Visit 4), and week 6 (Visit 5, exit) are listed in Appendix 16.1.1-Protocol Section 5.3.

9.5.2 Efficacy assessments

9.5.2.1 Assessment of efficacy

9.5.2.1.1 Percentage of COVID-19 patients turning negative and time taken to turn negative (RT-PCR)

RT-PCR were to be performed in each patients as described in Appendix 16.1.1Protocol-Section 9.1.1.

Two consecutive RT-PCR measurements were taken since days from admission until negative as mentioned in Appendix 16.1.1-Protocol-Section 8.1.

First measurement and time was recorded in the source document and in CRF. The same procedure was repeated as described in Appendix 16.1.1-ProtocolSection 9.4.

9.5.2.1.2 Time of convalescence and improvement in altered biomarkers post COVID-19 infection

9.5.2.1.2.1 Blood/Lymphatic system: C-reactive protein and Ferritin

CRPwas to be performed in each patient as described in Appendix 16.1.1Protocol-Section 9.1.2.

CRP was measured four times in the study as mentioned in Appendix 16.1.1Protocol-Section 8.1 and sample was collected as described in Appendix 16.1.1Protocol-Section 9.4.

Ferritinwas to be performed in each patient as described in Appendix 16.1.1Protocol-Section 9.1.3.

Ferritinwas measured three times in the study as mentioned in Appendix 16.1.1Protocol-Section 8.1and sample was collected as described in Appendix 16.1.1Protocol-Section 9.4.

9.5.2.1.2.2 Immunoglobulin's: Total Antibody COVID-19 (IgG & IgM)

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Total Antibody COVID-19 was to be performed in each patient as described in Appendix 16.1.1-Protocol-Section 9.1.4 and 9.1.5.

Total Antibody COVID-19 was measured four times in the study as mentioned in Appendix 16.1.1-Protocol-Section 8.1and sample was collected as described in Appendix 16.1.1-Protocol-Section 9.4.

9.5.2.1.2.3 Cytokines: IL-6

IL-6 was to be performed in each patient as described in Appendix 16.1.1Protocol-Section 9.1.6.

IL-6 was measured four times in the study as mentioned in Appendix 16.1.1Protocol-Section 8.1 and sample was collected as described in Appendix 16.1.1Protocol-Section 9.4.

9.5.2.1.2.4 Prognostic marker: D-Dimer

D-dimerwas to be performed in each patient as described in Appendix 16.1.1Protocol-Section 9.1.7.

D-dimerwas measured three times in the study as mentioned in Appendix 16.1.1Protocol-Section 8.1 and sample was collected as described in Appendix 16.1.1Protocol-Section 9.4.

9.5.2.1.2.5 Cardiac Injury: Troponin-I and Creatine Phosphokinase (CPK)

Troponin-Iwas to be performed in each patient as described in Appendix 16.1.1Protocol-Section 9.1.7.

Troponin-Iwas measured three times in the study as mentioned in Appendix 16.1.1-Protocol-Section 8.1 and sample was collected as described in Appendix 16.1.1-Protocol-Section 9.4.

CPK was to be performed in each patient as described in Appendix 16.1.1Protocol-Section 9.2.4.

CPK was measured four times in the study as mentioned in Appendix 16.1.1Protocol-Section 8.3 and sample was collected as described in Appendix 16.1.1Protocol-Section 9.4.

9.5.2.1.2.6 Lymphocyte subset counts: CD4+ T Cell, CD8+ T Cell, CD19+ B Cell, CD16+/CD56+ and NK Cell

CD4+ T Cell were to be performed in each patient as described in Appendix

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16.1.1-Protocol-Section 9.1.9, CD8+ T Cell as per Appendix 16.1.1-ProtocolSection 9.1.10, CD19+ B Cell as per Appendix 16.1.1-Protocol-Section 9.1.11, CD16+CD56+ NK Cell as per Appendix 16.1.1-Protocol-Section 9.1.12.

Lymphocyte subset counts was measured three times in the study as mentioned in Appendix 16.1.1-Protocol-Section 8.1 and sample was collected as described in Appendix 16.1.1-Protocol-Section 9.4.

9.5.2.1.2 Time to allaying a fever

The occurrence of fever was recorded and assessed as described in Appendix 16.1.1-Protocol-Section 8.2.

9.5.2.1.3 Arrest or delay in progression in asymptomatic to mild or moderate to severe to critical

The progression of the symptoms was recorded and assessed as described in Appendix 16.1.1-Protocol-Section 8.2.

9.5.2.1.4 Time to symptom relief

Patient reported improvement from influenza symptoms. The alleviation of influenza symptoms is defined as the time when all of 7 influenza symptoms (cough, sore throat, headache, nasal congestion, feverishness or chills, muscle or joint pain, and fatigue) have been assessed by the patient. Patient reported improvement using 4 scale; 0-none, 1-weak, 2-medium, 3-strong.The patient symptom score was recorded as described in Appendix 16.1.1-Protocol-Section 8.2

9.5.2.1.5 Days of treatment and hospitalization

The days of treatment and hospitalization were recorded along-side the RT-PCR as described in Appendix 16.1.1-Protocol-Section 9.1.1.

9.5.2.1.6 Incidence of respiratory failure and requirement of rescue

The Incidence of respiratory failure and requirement of rescue were recorded as described in Appendix 16.1.1-Protocol-Section 10.

9.5.2.1.7 Percent Mortality

The percent mortality was recorded and calculated at end of the study.

9.5.2. Appropriateness of efficacy assessments

Assessments described in the protocol are standard COVID-19 confirmatory and biomarker assessments for this indication and patient population.

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9.5.3 Safety assessments

9.5.3.1 Assessment of safety

Safety assessments consisted of collecting all adverse events (AEs), serious adverse events (SAEs), with their severity and relationship to study drug. Safety evaluation included vital signs (blood pressure, SpO2, pulse and respiratory rate), physical examination, haematological, biochemical, urinalysisand pregnancy test (for women of childbearing potential). Full information about the definition of AEs and SAEs, the procedures for reporting them is given in the Appendix 16.1.1-Protocol-Section 10andAppendix 16.1.1-Protocol-Section 9.2 for details of all safety assessments.

9.5.3.2 Appropriateness of safety assessments

The safety assessments selected are standard for this indication/patient population.

9.5.4 Other assessments

9.5.4.1 Radiological examinations: X-ray

Radiology was part of safety assessments, and was only performed at Screening and interventional Visits. Refer to Appendix 16.1.1-Protocol-Section 9.2 fordetails of these assessments.

9.5.4.2 PT (Prothrombin Time) & INR (International Normalized ratio)

PT-INR were part of safety assessments, and were only performed at Screening and interventional Visits. Refer to Appendix 16.1.1-Protocol-Section 9.2 for details of these assessments.

9.6 DATA QUALITY ASSURANCE

9.6.1 Monitoring

The responsibility for site monitoring resided with the Ethix Pharma's field monitors. Details of the monitoring procedures are described in Appendix 16.1.1Protocol-Section 13.1.

9.6.2 Data collection

Designated Investigator staff entered the data required by the protocol into paper CRF with in-house QMS system. They were not given access to the CRF until adequately trained. Documented training on CRF and Protocol was completed by the designated study staff before the study initiation.

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9.6.3 Database management and quality control

Ethix Pharma staff reviewed the data entered into the CRFs by investigational staff for completeness and accuracy and instructed the site personnel to make any required corrections or additions.

Queries were sent to the investigational site using an email query. Designated Investigator site staff was required to respond to each query and confirm or correct the data. Concomitant medications entered into the log as per SOP.

Randomization codes and data about all study treatment dispensed to the patient were tracked.

9.6.4 Quality assurance and auditing

There were 2-remote audits or inspections along with one physical audit conducted at sites participating in this study.

9.7 STATISTICAL METHODS PLANNED IN THE PROTOCOL AND DETERMINATION OF SAMPLE SIZE

This section describes the statistical analyses that were planned as per the protocol and statistical analysis plan (SAP). See Section 9.8.3 where the changes in planned analyses and the reason for them are detailed.

9.7.1 Data analysis

9.7.2 Analysis sets

The analysis sets defined as per the protocol and SAP were:

All enrolled analysis set included all patients who signed an Informed Consent Form (ICF) and were assigned patient numbers. This analysis set was used to summarize patient disposition and pre-treatment AEs.

All randomized analysis set included all enrolled patients who were randomized to treatment. Safety analysis set: included all patients exposed to at least one dose of any study therapy. Patients in the safety analysis set were analyzed according to the treatment received.

Full Analysis Set (FAS) included all randomized patients with efficacy measurement at baseline who had at least one on-treatment assessment. This analysis set was an analysis for all primary and secondary endpoints. Patients in the FAS were analyzed according to randomized treatment.

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Per protocol analysis set (PPS) a subset of all patients in the FAS and excluded all data which met any of the critical deviation criteria identified in the SAP. In addition, individual patient visits and data points that did not satisfy protocol criteria were excluded from the PPS.

The final patient evaluability was determined prior to locking the database.

9.7.3 Patient disposition, demographics and other baseline characteristics

All patients who signed informed consent were accounted in patient disposition. Patient disposition table were to present the number and percentage of patients for the following:

- Screened/Run in
- Screen/ Run in Failure
- Entered the randomization phase
- Completed the randomization phase
- Discontinued the randomization phase
- Reason for discontinuation

Details of the planned data analysis for patient demographics and other baseline characteristics are presented in Appendix 16.1.1-Protocol-Section 11.1.

9.7.4 Treatments (study drug, rescue medication, other concomitant therapies, compliance)

Data for study drug administration and concomitant therapies were to be listed by treatment group and patient. Extent of exposure, as a continuous variable and categorically, was to be analyzed with summary statistics, using the Safety Analysis Set.

9.7.5 Analysis of the primary efficacy variables

9.7.5.1 Variable

The primary efficacy endpoint in this study was the percentage of patients getting COVID-19 RT-PCR negative and time taken to get the same from days from admission, days from first testing positive, days from first noticed symptoms.

The other primary efficacy endpoint in this study was the change from baseline (CFB) to day5, 12 and 45 in CRP, Total Antibody, IL-6 and change from baseline (CFB) to day12 and 45 in Ferritin, D-dimer, Troponin 1, CD4+ T cell, CD8+ T cell, CD19+ B cell, CD16+ CD56+ NK cell.

CFB inbiomarkers = improvement in altered biomarkers post COVID-19infection.

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The primary analysis set for the efficacy analysis was the FAS.

9.7.5.2 Statistical hypothesis, model, and method of analysis

Refer to Appendix 16.1.1-Protocol Section 11.1.

9.7.5.3 Supportive analyses

The primary analysis was planned to be repeated using the per protocol set in order to assess its robustness in regard to deviations.

9.7.6 Analysis of secondary efficacy variables

9.7.6.1 Efficacy

Analyses of treatment differences of secondary endpoints was planned to use the same methods as those for the primary endpoint. Hypothesis tests were to usethe same null and alternative hypotheses with μ representing the mean for the variable being tested.

See Appendix 16.1.1-Protocol-Section 11.1 for details of the planned statistical analysis of secondary efficacy endpoints.

9.7.7 Safety analyses

The planned safety analyses consisted of descriptive summaries of the data as relevant to the scale of data, e.g., frequency and percent for adverse events, and mean changes from baseline as appropriate.

Frequency and percentage of patients were provided for each categorical variable by treatment group.

9.7.8 Handling of missing values/censoring/discontinuations

Missing observations were not imputed. The statistical models that were employed and the associated analyses were robust under the missing completely at random and the missing at random assumptions.

9.7.9 Sample size calculation

With 62 evaluable patients per treatment group in the primary efficacy analysis, there was approximately 80% power to detect percent change from baseline in getting COVID-19 RT-PCR negative between the treatment groups. This calculation was based on the assumption of a common standard deviation for mean and the use of a twosample two-sided t-test performed at the $\alpha = 0.05$ level of significance.

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Assuming a drop-out rate of 10%, approximately 62 patients per treatment group were to be randomized to ensure the required number of evaluable patients in the final efficacy analysis.

9.7.10 Power for analysis of key secondary variables

Not applicable

9.7.11 Interim analysis

No formal interim analysis was planned for this study.

9.8 CHANGES IN THE CONDUCT OF THE STUDY OR PLANNED ANALYSES

9.8.1 Protocol amendments

The study protocol was amended once. The original protocol and amendment are provided in Appendix 16.1. Previous sections of this report describe the study conduct as amended. The key features of Amendment 1 (28-Sep-2020) are given below:
Amendment 1 introduced the following changes:

- Section 5.5Dosage and Treatment schedule: added the total quantity of Vedicinals-9 suspension to be consumed by each patient in the Vedicinals9+standard care group and described the standard treatment according to the guidelines of Ministry of Health and Family Welfare and PI's discretion as per patient health status and medical history.
- Section 7Investigational Product: Mentioned the standard care product and their dosage and administration.
- Section 7.4 IP Packing & labelling: added the total quantity of Vedicinals9 suspension to be consumed by each patient in the Vedicinals-9+standard care group.
- Section 17 Annexure I: Added the chart for Clinical Guidance for Management of COVID-19 confirmed cases.
- Other editorial changes

9.8.2 Other changes in study conduct

See Section 9.4.9.

9.8.3 Changes in planned analysis

No changes in planned efficacy and safety analyses.

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The patient data reports generated from the clinical database reporting efficacy measure and key safety data are the only results presented in this report.

10 STUDY PATIENTS

10.1 DISPOSITION OF PATIENTS

During the conduct of the study, 136 patients screened out of which 124 patients at 2 participating centres in India had had signed the Informed Consent Form. Of these 124 patients:

- 124 patients completed screening and were in the run-in phase124 patientswere randomized, taking open-label either standard medication alone or in adjunction with Vedicinals-9
- 1 patient was discontinued from the day 12 of the study
- 4 patients lost to follow-up on the day-45 of the study

See section 11.2Disposition, Demographic and Other Baseline Characteristics

10.2 PROTOCOL DEVIATIONS

Two subjects (ID 0105 and 0103) were deviated from their scheduled visit on day 14 and 45 day to day 16 and 49 respectively. Appendix 16.2.2.

11 EFFICACY EVALUATION

11.1 DATA SETS ANALYZED

All enrolled analysis set, all randomized analysis set, full analysis set (FAS) n=124 and Per protocol analysis set (PPS)n= 119. Refer section 9.7.2.

11.2 DISPOSITION, DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS

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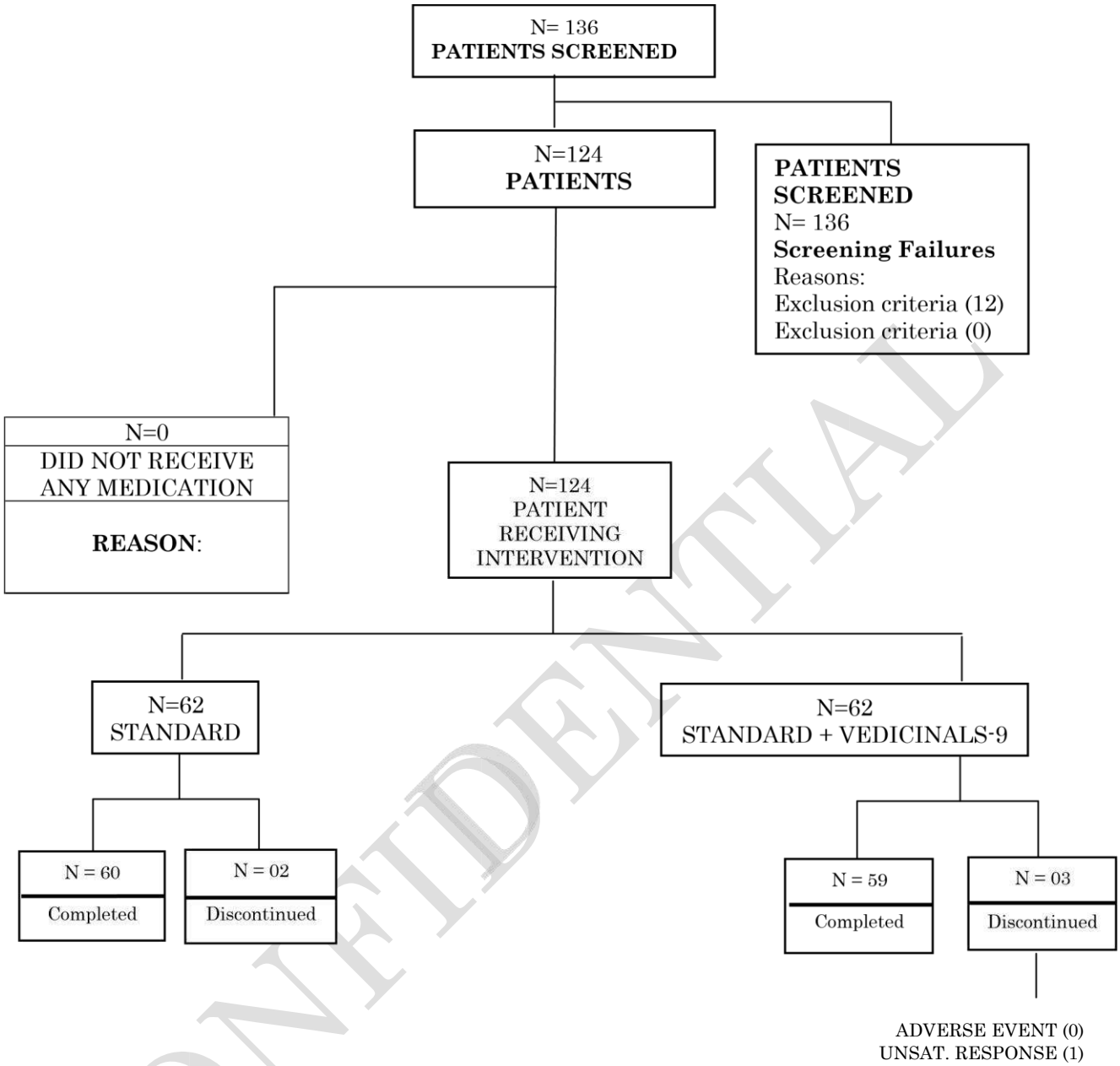

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Fig 11-0 Disposition and other baseline characteristics

11.3 MEASUREMENTS OF TREATMENT COMPLIANCE

To be included.

11.4 EFFICACY RESULTS AND TABULATIONS OF INDIVIDUAL PATIENT DATA

11.4.1 Analysis of efficacy

11.4.1.1 Primary efficacy results

11.4.1.1.1 Percentage of COVID-19 patients turning negative and time taken to turn negative (RT-PCR)

Table 11-1 Percentage of COVID-19 patients turning negative and time taken to turn negative

Outcome In Days	Expected %	Standard (S) Observed %	Vedicinals-9 + Standard (SV9) Observed %	Time Taken C. Days
Day 0-4	25.00	1.613	29.03*	4 days
Day 5-11	70.00	37.10	48.39*	11 days
Day 12-14	5.000	61.29	22.58*	14 days
Total	100.0	100.00	100.00	

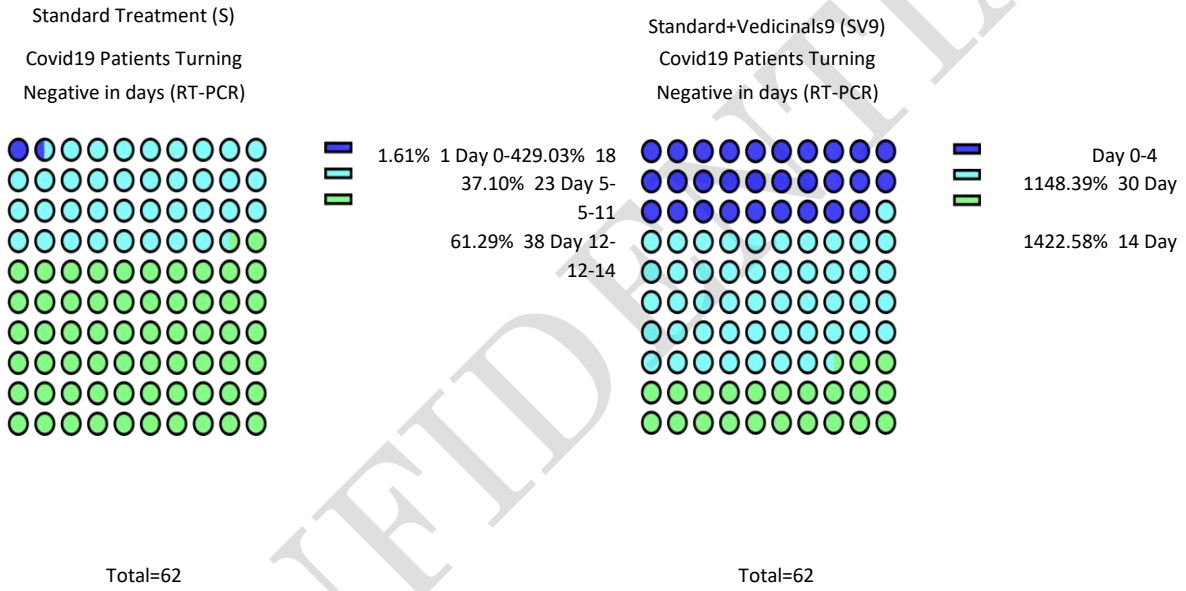

Fig 11-1aEffect of VEDICINALS-9 on COVID-19 positive patient's turning negative in days (RTPCR) from day 0 to 14. Data interpret following: comparison of number of patients turning negative in0-4, 5-11 and 12-14 days, when vedicinals-9 (5000mg) adjuvant with standard intervention compared with standard intervention alone. Data represented as change in expected and observed values in two comparable interventional group (n=62 per group). Significant at *P<0.05, when compared before and after intervention at 0-4, 5-11 and 12-14 daysin both interventional groups. [Chi-Square test for proportions].

The percentage of COVID-19 positive patient's (RT-PCR) turning negative in 0-4, 5-11, 12-14 days were 29.03%, 48.39% and remaining 22.58% respectively in Vedicainals-9 adjuvant group compared to the standard treatment alone group 1.61%, 37.10% and remaining 61.29% respectively. The results show more patients getting negative in first 5 days in Vedicainals-9 adjuvant group compared to standard alone group.

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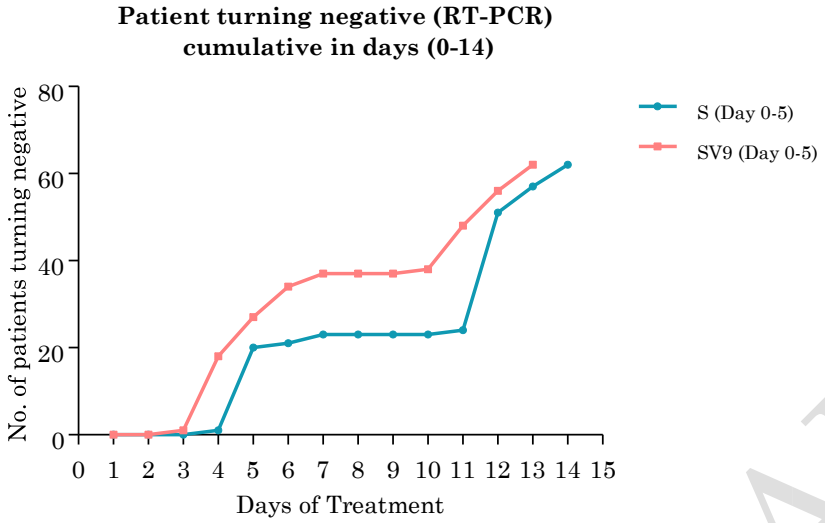

Fig 11-1b Cumulative no. of COVID-19 patients turning negative in days (RT-PCR)

Table 11-2 Mean days of COVID-19 patients staying positive

COVID-19 patients staying positi ve		
Intervention	**Day 0-14 (Mean ± SEM)**	***p*- value**
Standard (S)	9.71±0.45	
Vedicinals9 + Standard (SV9)	7.62±0.45	**P<0.01

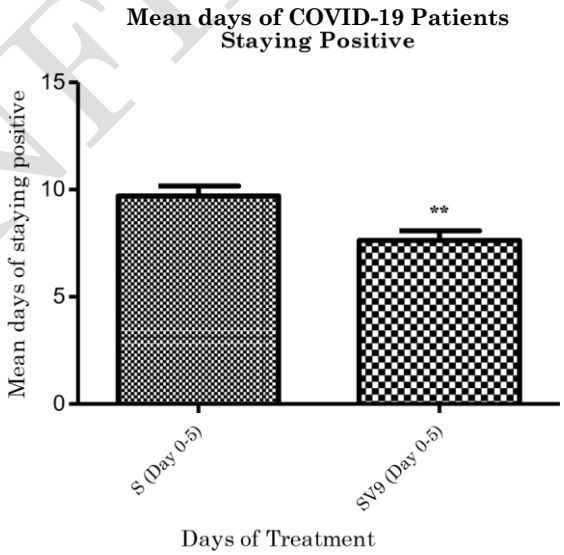

Fig 11-2Effect of VEDICINALS-9 on COVID-19 patients at risk (*staying positive*) from day 0 to 14. Data interpret following: comparison of mean difference in patients remaining positivefrom day 0 to 14, when vedicinals-9 (5000mg) adjuvant with standard intervention compared with standard intervention alone. Data represented as change in number of patients remaining positive (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at

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*p<0.05, **p<0.01, when compared before and after intervention in both interventional groups. [Unpaired t test with Welch's correction]

*The mean number of COVID-19 patients at risk (staying positive) from day 0 to 14 is significantly low (7.62±0.45, **P 0.0015) in Vedicainals-9 adjuvant group compared to the standard treatment alone group (9.71±0.45).*

Table 11-3 Covid-19 patients CT value (Viral Load RT-PCR)

CT Value (Viral Load RT-PCR)		
Intervention	**Day 0-5 (Mean ± SEM)**	***p*- value**
Standard (S)	1.399±0.092	
Vedicinals9 + Standard (SV9)	1.762±0.125	*P<0.05

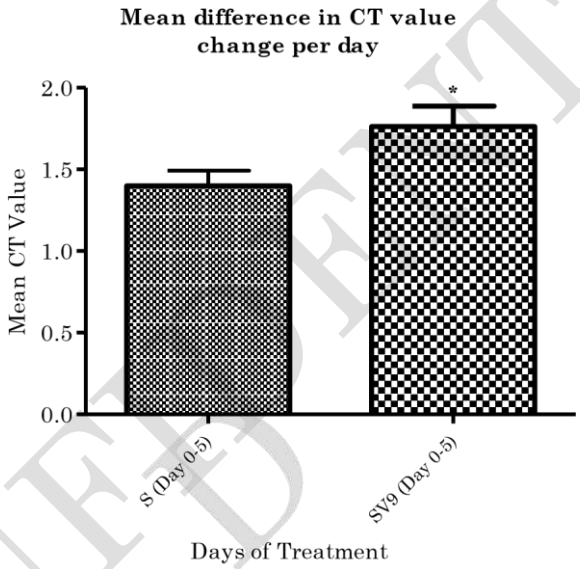

Fig 11-3Effect of VEDICINALS-9 on CT value (*Viral Load*) of COVID-19 positive patients from day 0 to 5. Data interpret following: comparison of mean difference in CT value per day (*Viral Load*) from day 0 to 5, when vedicinals-9 (5000mg) adjuvant with standard intervention compared with standard intervention alone. Data represented as change in CT value (*Viral Load*) levels (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, when compared before and after intervention at day 5 both interventional groups. [Unpaired t test with Welch's correction]

*The improvement (Increase) in mean CT value (Viral Load) of COVID-19 positive patients from day 0 to 5 was significant (1.762±0.125, *P<0.05) in Vedicainals-9 adjuvant group compared to the standard treatment alone (1.399±0.092).*

11.4.1.1.2 Time of convalescence and improvement in altered biomarkers post COVID-19 infection

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11.4.1.1.2.1 Blood/Lymphatic system: C-reactive protein and Ferritin

Table 11-4 Improvement in CRP post COVID-19 infection

C-reactive protein (CRP) (mg/L)							
Intervention	**Mean ± SEM**				***p*- value**		
	Day 0	**Day 5**	**Day 12**	**Day 45**	**Day 0 Vs 5**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	12.04±0.87	9.23±0.49	5.15±0.32	3.54±0.18	** (<0.01)	*** (<0.001)	*** (<0.001)
Vedicinals9 + Standard (SV9)	10.29±1.44	6.93±0.47	5.04±0.32	3.33±0.18	*** (<0.001)	*** (<0.001)	*** (<0.001)

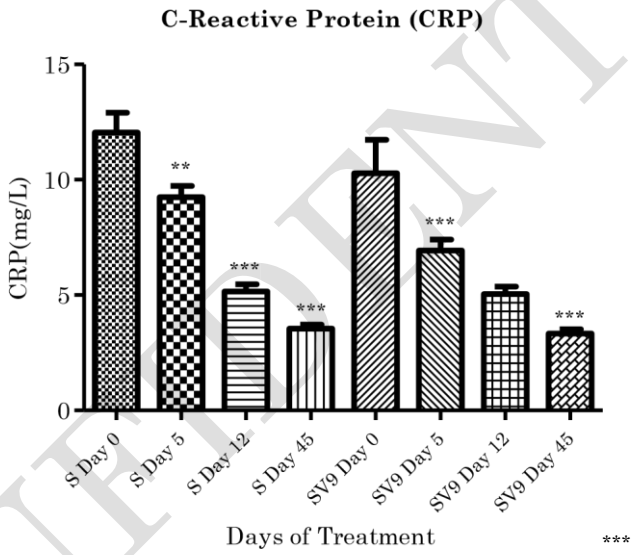

Fig 11-4 Effect of VEDICINALS-9 on serum CRP levels (mg/L) of COVID-19 positive patients from day 0 to 5, 12 and 45. Data interpret following: comparison of serum CRP levels (mg/L) from day 0 to 5, 12 and 45, when vedicinals-9 (5000mg) adjuvant with standard intervention compared with standard intervention alone. Data represented as change in serum CRP levels (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001 when compared before and after intervention at day 5, 12 and 45 in both interventional groups. [One-way ANOVA followed by dunnett's multiple comparison test]

*The improvement (decrease) in mean serum CRP levels (mg/L) of COVID-19 positive patients from day 0 to 5, 12 and 45was significant (10.29±1.44 to 6.93±0.47, ***P<0.001), (5.04±0.32, ***P<0.001) and (3.33±0.18, ***P<0.001)in Vedicainals-9 adjuvant group compared to the standard treatment alone (12.04±0.87 to 9.23±0.49, **P<0.01), (5.15±0.32, ***P<0.001) and (3.54±0.18, ***P<0.001).*

Table 11-5aImprovement in Ferritin (ID)post COVID-19 infection

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Ferritin [ID] (µg/L)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	14.57±2.18	36.02±13.02	62.13±09.45	ns	*p<0.05
Vedicinals9 + Standard (SV9)	12.71±2.09	47.24±22.12	67.83±16.35	*p<0.05	**p<0.01

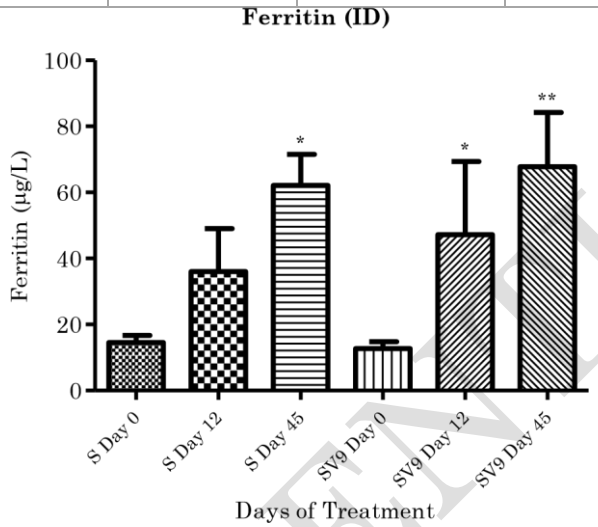

Fig 11-5aEffect of VEDICINALS-9 on serum ferritin levels (µg/L) of COVID-19 positive patients having iron deficiency from day 0 to 12 and 45. Data interpret following: comparison of serum ferritin levels (µg/L) from day 0 to 12 and 45, when vedicinals-9 (5000mg) adjuvant with standard intervention compared with standard intervention alone. Data represented as change in serum ferritin levels in iron deficient patients (Mean ± SEM) in two comparable interventional group (n=62 per group). Non-Significant at *p<0.05, **p<0.01, when compared before and after intervention at day 12 and 45 in both interventional groups. [One-way ANOVA followed by dunnett's multiple comparison test].

Table 11-5bImprovement in Ferritin (IO)post COVID-19 infection

Ferritin [IO] (µg/L)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	541.5±40.89	295.7±11.68	142.8±15.04	***p<0.001	***p<0.001
Vedicinals9 + Standard (SV9)	558.5±52.71	262.6±46.11	152.0±18.14	***p<0.001	***p<0.001

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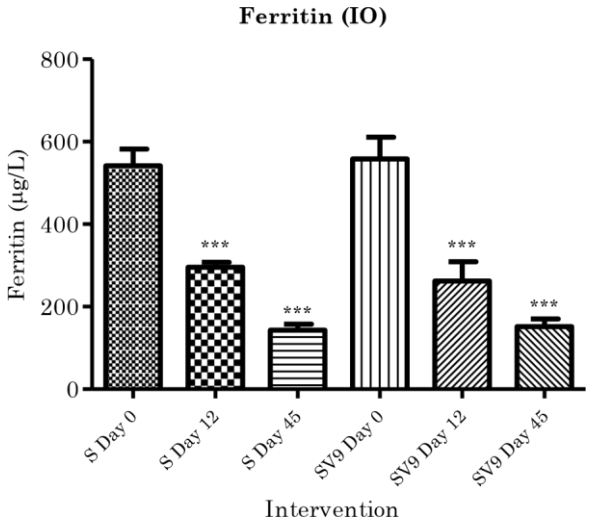

Fig 11-5bEffect of VEDICINALS-9 on serum ferritin levels (µg/L) of COVID-19 positive patients having excess iron from day 0 to 12 and 45. Data interpret following: comparison of serum ferritin levels (µg/L) from day 0 to 12 and 45, when vedicinals-9 (5000mg) adjuvant with standard intervention compared with standard intervention alone. Data represented as change in serum ferritin levels in iron excess patients (Mean ± SEM) in two comparable interventional group (n=62 per group). Non-Significant at *p<0.05, **p<0.01, when compared before and after intervention at day 12 and 45 in both interventional groups. [One-way ANOVA followed by dunnett's multiple comparison test].

Table 11-5cImprovement in Ferritin (NI)post COVID-19 infection

Ferritin [NI] (µg/L)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	50.10±06.87	56.57±4.32	192.9±14.40	ns	***p<0.001
Vedicinals9 + Standard (SV9)	91.29±12.67	94.50±13.77	162.7±13.56	ns	***p<0.001

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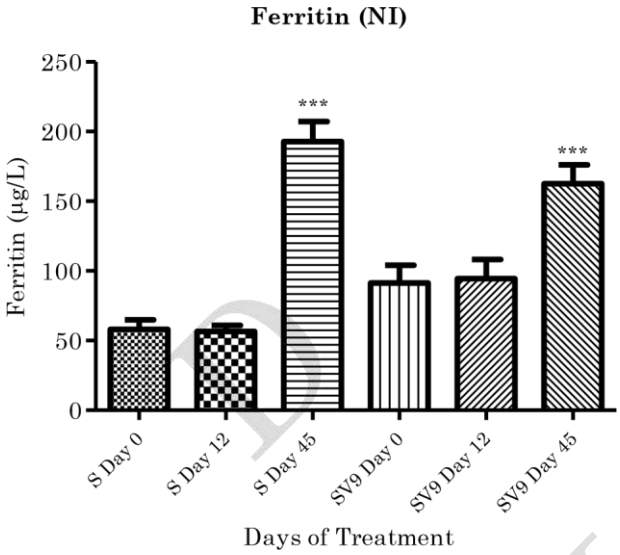

Fig 11-5cEffect of VEDICINALS-9 on serum ferritin levels (µg/L) of COVID-19 positive patients having normal iron from day 0 to 12 and 45. Data interpret following: comparison of serum ferritin levels (µg/L) from day 0 to 12 and 45, when vedicinals-9 (5000mg) adjuvant with standard intervention compared with standard intervention alone. Data represented as change in serum ferritin levels in iron excess patients (Mean ± SEM) in two comparable interventional group (n=62 per group). Non-Significant at *p<0.05, **p<0.01, ***p<0.001 when compared before and after intervention at day 12 and 45 in both interventional groups. [One-way ANOVA followed by dunnett's multiple comparison test].

*The improvement (Increase) in mean serum Ferritin levels (µg/L) of COVID-19 positive patientshaving iron deficiencyfrom day 0 to 12 and 45 was significant (12.71±2.09 to 47.24±22.12 and 67.83±16.35, *p<0.5 and **p<0.01) in Vedicainals-9 adjuvant group compared to the standard treatment alone (14.57±2.18 to 36.02±13.02 and 62.13±09.45, p>0.5 (ns) and *p<0.05).*

*The improvement (decrease) in mean serum Ferritin levels (µg/L) of COVID-19 positive patientshaving excess ironfrom day 0 to 12 and 45 was significant (558±52.71 to 262.6±46.11 and 152.0±18.14, ***p<0.001 and ***p<0.001) in Vedicainals-9 adjuvant group compared to the standard treatment alone (541.5±40.89 to 295.7±11.68 and 142.8±15.04, ***p<0.001 and ***p<0.001).*

*The improvement (Increase) in mean serum Ferritin levels (µg/L) of COVID-19 positive patients having normal iron from day 0 to 12 and 45 was significant (91.29±12.67 to 94.50±13.77 and 162.7±13.56, p>0.05 (ns) and ***p<0.001) in Vedicainals-9 adjuvant group compared to the standard treatment alone (50.10±06.87 to 56.57±4.32 and 192.9±14.40, p>0.05 (ns) and ***p<0.001).*

11.4.1.1.2.2 Immunoglobulin's: Total Antibody COVID-19 (IgG & IgM)

Table 11-6 Improvement in Total Antibody COVID-19 (IgG & IgM) post COVID-19 infection

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Total Antibody COVID-19 (IgG & IgM)							
Intervention	**Mean ± SEM**				***p*- value**		
	Day 0	**Day 5**	**Day 12**	**Day 45**	**Day 0 Vs 5**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	1.92±0.37	3.64±0.72	3.63±0.27	11.23±1.15	ns	ns	**p<0.01
Vedicinals9 + Standard(SV9)	2.61±0.42	5.02±0.47	5.97±0.46	13.64±1.44	*p<0.05	*p<0.05	**p<0.01

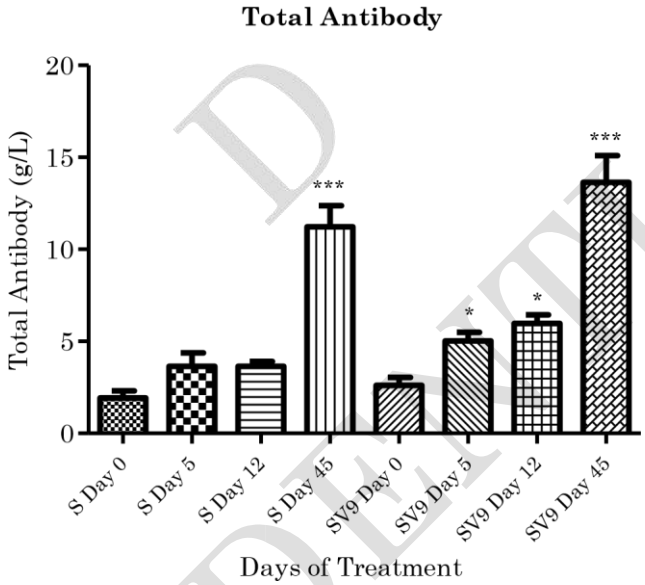

Fig 11-6 Effect of VEDICINALS-9 on serum Total antibody levels of COVID-19 positive patients from day 0 to 5, 12 and 45. Data interpret following: comparison of serum Total antibody levels from day 0 to 5, 12 and 45, when vedicinals-9 (5000mg) adjuvant with standard intervention compared with standard intervention alone. Data represented as change in serum Total antibody levels (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, when compared before and after intervention at day 5, 12 and 45 in both interventional groups. [One-way ANOVA followed by dunnett's multiple comparison test]

*The improvement (Increase) in mean serum Total antibody levels (g/L) of COVID19 positive patients from day 0 to 5, 12 and 45was significant (2.61±0.42 to 5.02±0.47, 5.97±0.46 and 13.64±1.44, *p<0.05, *p<0.05**p<0.01)in Vedicainals-9 adjuvant group compared to the standard treatment alone (1.92±0.37to 3.64±0.72, 3.63±0.27 and 11.23±1.15, p>0.05(ns), p>0.05(ns) and **p<0.01).*

11.4.1.1.2.3 Cytokines: IL-6

Table 11-7Improvement in IL-6 (pg/mL)post COVID-19 infection

Interleukin-6 (IL-6) (pg/mL)		
Intervention	**Mean ± SEM**	***p*- value**

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	Day 0	Day 5	Day 12	Day 45	Day 0 Vs 5	Day 0 Vs 12	Day 0 Vs 45
Standard (S)	12.48±4.53	5.91±1.53	6.18±1.83	2.98±0.68	ns	ns	**p<0.01
Vedicinals9 + Standard(SV9)	12.79±5.35	4.01±0.36	3.62±0.39	2.70±0.24	*p<0.05	*p<0.05	**p<0.01

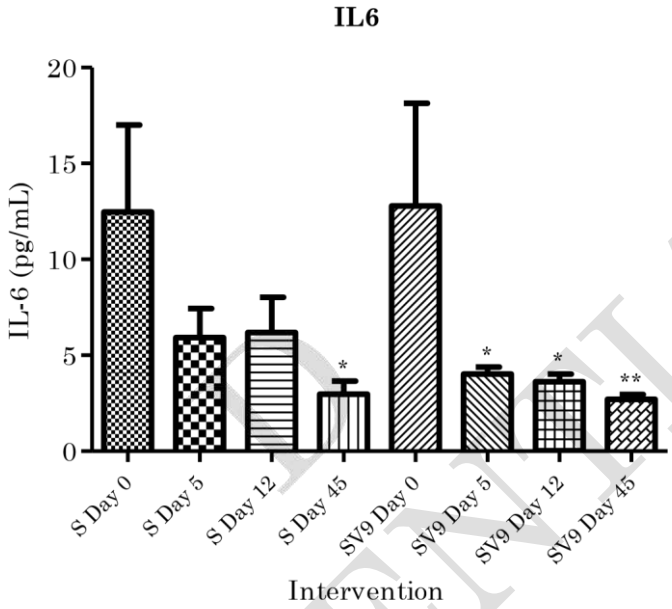

Fig 11-7 Effect of VEDICINALS-9 on serum IL-6 levels (pg/mL) of COVID-19 positive patients from day 0 to 5, 12 and 45. Data interpret following: comparison of serum IL-6 levels (pg/mL) from day 0 to 5, 12 and 45, when vedicinals-9 (5000mg) adjuvant with standard intervention compared with standard intervention alone. Data represented as change in serum IL-6 levels (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, when compared before and after intervention at day 5, 12 and 45 in both interventional groups. [One-way ANOVA followed by dunnett's multiple comparison test]

*The improvement (decrease) in mean serum IL-6 levels (pg/mL) of COVID-19 positive patients from day 0 to 5, 12 and 45 was significant (12.79±5.35 to 4.01±0.36, 3.62±0.39 and 2.70±0.24, *p<0.05, *p<0.05 **p<0.01)in Vedicainals-9 adjuvant group compared to the standard treatment alone (12.48±4.53 to 5.91±1.53, 6.18±1.83 and 2.98±0.68, p>0.05(ns), p>0.05(ns) and **p<0.01).*

11.4.1.1.2.4 Prognostic marker: D-Dimer

Table 11-8 Improvement in D-dimer post COVID-19 infection

D-dimer (µg FEU/L)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	410.8±45.67	687.7±187.2	285.4±12.34	ns	ns

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Vedicinals9 + Standard (SV9)	416.7±43.45	351.8±28.48	261.5±14.15	ns	**p<0.01

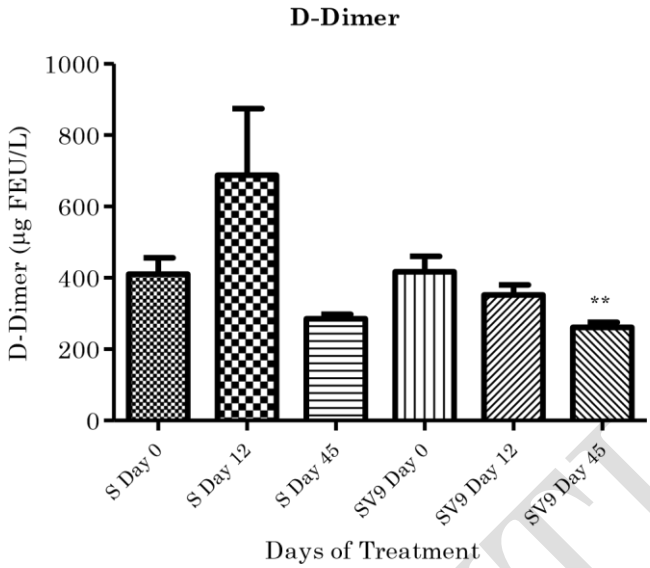

Fig 11-8 Effect of VEDICINALS-9 on serum D-Dimer levels (µg FEU/L) of COVID-19 positive patients from day 0 to 12 and 45. Data interpret following: comparison of serum D-Dimer levels (µg FEU/L) from day 0 to day 12 and 45, when vedicinals-9 (5000mg) adjuvant with standard intervention compared with standard intervention alone. Data represented as change in serum D-Dimer levels (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, when compared before and after intervention at day 12 and 45 in both interventional groups. [One-way ANOVA followed by dunnett's multiple comparison test].

*The improvement (decrease) in mean serum D-Dimer levels (µg FEU/L) of COVID-19 positive patients from day 0 to 12 and 45 was significant (416.7±43.45 to 351.8±28.48 and 261.5±14.15, p>0.05 (ns) and ***p<0.001) in Vedicainals-9 adjuvant group compared to the standard treatment alone (410.8±45.67 to 687.7±187.2 and 285.4±12.34, p>0.05 (ns) and p>0.05 (ns).*

11.4.1.1.2.5 Cardiac Injury: Troponin-I & Creatine Phosphokinase (CPK)

Table 11-9 Improvement in CPK post COVID-19 infection

Creatine Phosphokinase (CPK) (U/L)							
Intervention	**Mean ± SEM**				***p*- value**		
	Day 0	**Day 5**	**Day 12**	**Day 45**	**Day 0 Vs 5**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	78.45±5.35	71.63±3.78	68.91±4.73	131.5±5.3	ns	ns	*p<0.05
Vedicinals-9 + Standard(SV9)	109.1±21.65	96.84±16.84	76.57±5.34	124.1±5.7	ns	**p<0.01	ns

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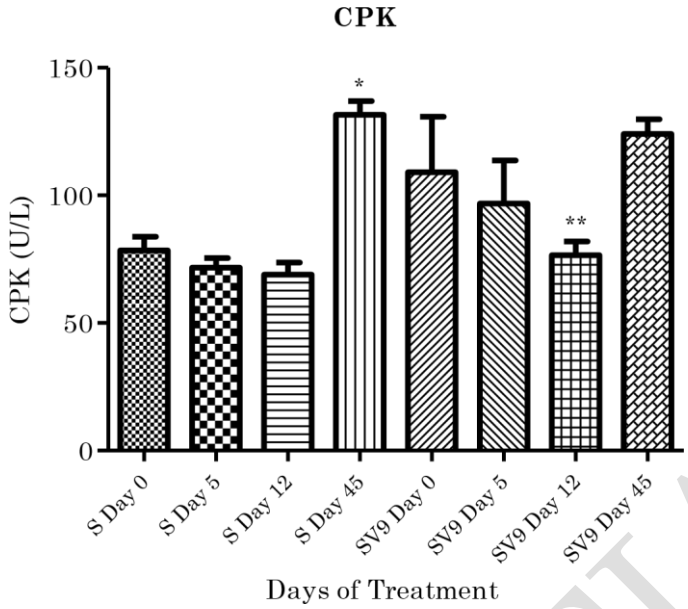

Fig 11-9 Effect of VEDICINALS-9 on serum CPK levels (U/L) of COVID-19 positive patients from day 0 to 5, 12 and 45. Data interpret following: comparison of serum CPK levels (U/L) from day 0 to 5, 12 and 45, when vedicinals-9 (5000mg) adjuvant with standard intervention compared with standard intervention alone. Data represented as change in serum CPK levels (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, when compared before and after intervention at day 5, 12 and 45 in both interventional groups. [Oneway ANOVA followed by dunnett's multiple comparison test]

*The improvement (decrease) in serum CPK levels (U/L) of COVID-19 positive patients from day 0 to 5, 12 and 45 was significant (109.1±21.65 to 96.84±16.84, 76.57±5.34 and 124.1±5.7, p>0.05 (ns), **p<0.01)in Vedicainals-9 adjuvant group compared to significant (increase) in standard treatment alone (78.45±5.35to 71.63±3.78, 68.91±4.73and 131.5±5.3, p>0.05(ns), p>0.05(ns) and *p<0.05).*

11.4.1.1.2.6 Lymphocyte subset counts: CD4+ T Cell, CD8+ T Cell, CD19+ B Cell, CD16+/CD56+ and NK Cell

Table 11-10 Improvement in CD4+ T cell post COVID-19 infection

CD4+ T (cells/µL)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	1190±67.65	1607±107.9	1655±117.5	*p<0.05	*p<0.05
Vedicinals9 + Standard (SV9)	957.6±69.24	1201±94.19	1289±115.2	**p<0.01	**p<0.01

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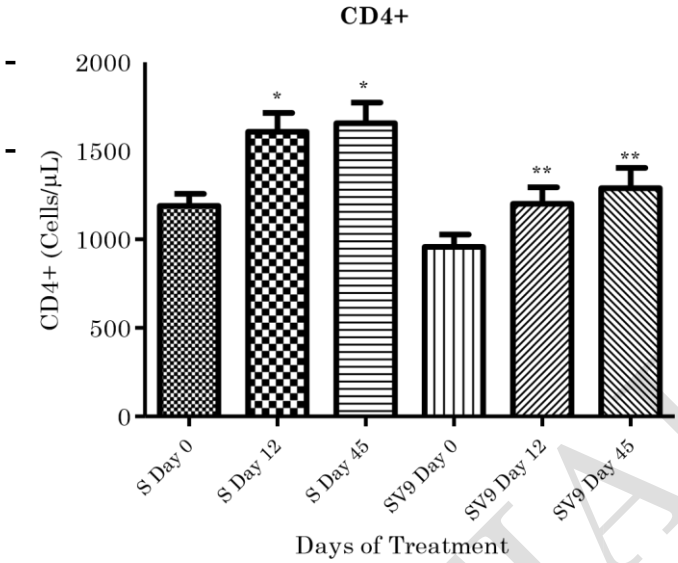

Fig 11-10 Effect of VEDICINALS-9 on serum CD4+ levels (cells/µL) of COVID-19 positive patients from day 0 to 12 and 45. Data interpret following: comparison of serum CD4 levels (µg/L) from day 0 to 12 and 45, when vedicinals-9 (5000mg) adjuvant with standard intervention compared with standard intervention alone. Data represented as change in serum CD4+ levels (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, when compared before and after intervention at day 12 and 45 in both interventional groups. [One-way ANOVA followed by dunnett's multiple comparison test].

*The improvement (Increase) in mean serum CD4+ levels (cells/µL) of COVID-19 positive patients from day 0 to 12 and 45 was significant (957.6±69.24 to 1201±94.19 and 1289±115.2, **p<0.01 and **p<0.01) in Vedicainals-9 adjuvant group compared to the standard treatment alone (1190±67.65 to 1607±107.9 and 1655±117.5, *p<0.05 and *p<0.05).*

Table 11-11 Improvement in CD8+ T cell post COVID-19 infection

CD8+ T (cells/µL)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	1002±68.70	1329±105.5	1370±117.5	*p<0.05	*p<0.05
Vedicinals9 + Standard (SV9)	797±65.43	1094±105.2	1113±103.5	*p<0.05	*p<0.05

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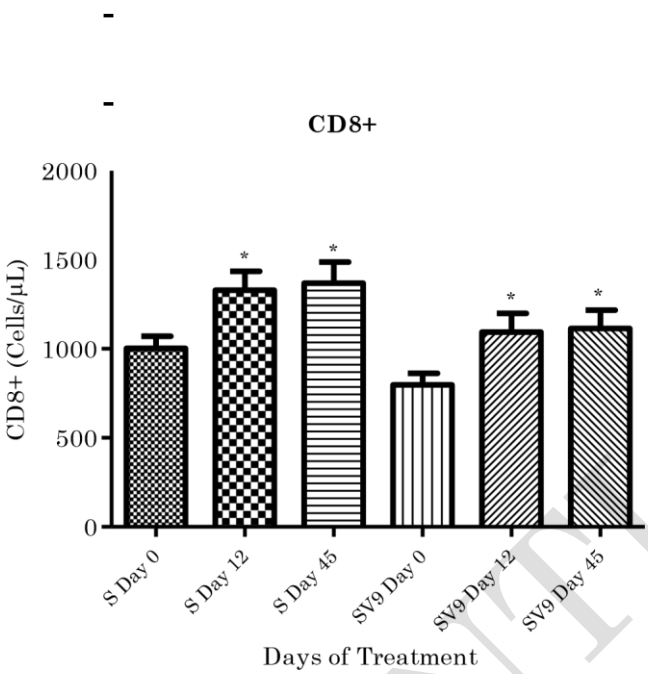

Fig 11-11 Effect of VEDICINALS-9 on serum CD8+ levels (cells/µL) of COVID-19 positive patients from day 0 to 12 and 45. Data interpret following: comparison of serum CD8+ levels (µg/L) from day 0 to 12 and 45, when vedicinals-9 (5000mg) adjuvant with standard intervention compared with standard intervention alone. Data represented as change in serum CD8+ levels (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, when compared before and after intervention at day 12 and 45 in both interventional groups.
[One-way ANOVA followed by dunnett's multiple comparison test].

*The improvement (Increase) in mean serum CD8+ levels (cells/µL) of COVID-19 positive patients from day 0 to 12 and 45 was significant (797±65.43 to 1094±105.2 and 1113±103.5, *p<0.05 and *p<0.05) in Vedicainals-9 adjuvant group compared to the standard treatment alone (1002±68.70 to 1329±105.5 and 1370±117.5, *p<0.05 and *p<0.05).*

Table 11-12 Improvement in CD19+ B cell post COVID-19 infection

CD19+ B cell (cells/µL)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	263.5±28.30	241.3±19.06	194.8±15.83	ns	ns

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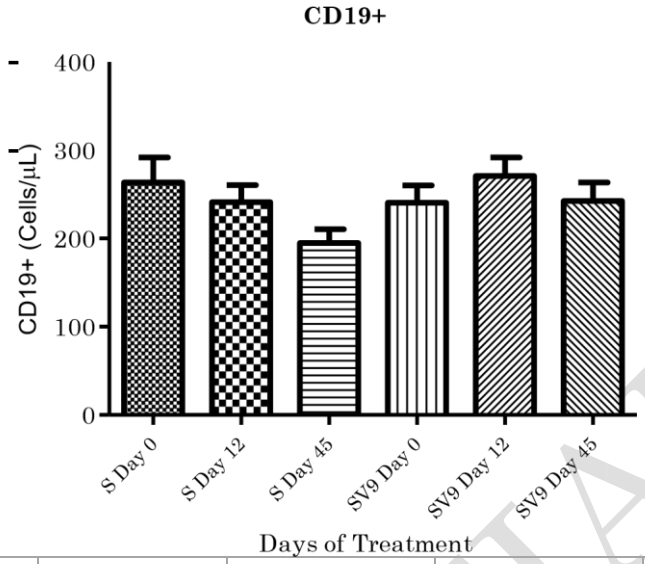

Vedicinals9 + Standard (SV9)	240.6±19.55	270.8±20.88	242.5±21.09	ns	ns

Fig 11-12Effect of VEDICINALS-9 on serum CD19+ levels (cells/µL) of COVID-19 positive patients from day 0 to 12 and 45. Data interpret following: comparison of serum CD19+ levels (µg/L) from day 0 to 12 and 45, when vedicinals-9 (5000mg) adjuvant with standard intervention compared with standard intervention alone. Data represented as change in serum CD19+ levels (Mean ± SEM) in two comparable interventional group (n=62 per group). Non-significant (ns) at P>0.05, when compared before and after intervention at day 12 and 45 in both interventional groups. [One-way ANOVA followed by dunnett's multiple comparison test].

The improvement (Increase) in mean serum CD19+ levels (cells/µL) of COVID-19 positive patients from day 0 to 12 and 45 was non-significant (240.6±19.55 to 270.8±20.88 and 242.5±21.09, p>0.05 (ns) and p>0.05 (ns) in Vedicainals-9 adjuvant group compared to the standard treatment alone (263.5±28.30 to 241.3±19.06 and 194.8±15.83, p>0.05 (ns) and p>0.05 (ns).

Table 11-13 Improvement in CD16+ 56+ NK cell post COVID-19 infection

CD16+/56+ NK cells (cells/µL)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**

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Standard (S)	230.3±24.08	216.5±22.61	179.6±18.09	ns	ns
Vedicinals9 + Standard (SV9)	205.1±17.73	246.8±21.72	219.7±19.51	ns	ns

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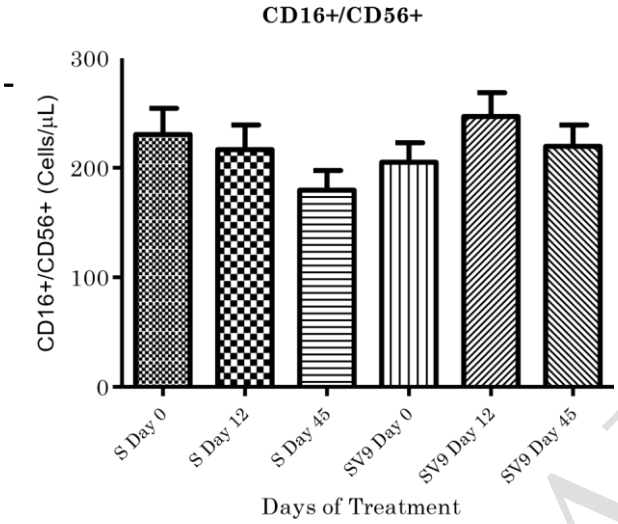

Fig 11-13Effect of VEDICINALS-9 on serum CD16+/56+ levels (cells/µL) of COVID-19 positive patients from day 0 to 12 and 45. Data interpret following: comparison of serum CD16+/56 levels (µg/L) from day 0 to 12 and 45, when vedicinals-9 (5000mg) adjuvant with standard intervention compared with standard intervention alone. Data represented as change in serum CD16+/56+ levels (Mean ± SEM) in two comparable interventional group (n=62 per group). Non-significant (ns) at P>0.05, when compared before and after intervention at day 12 and 45 in both interventional groups. [One-way ANOVA followed by dunnett's multiple comparison test].

The improvement (Increase) in mean serum CD16+/56+ NK levels (cells/µL) of COVID-19 positive patients from day 0 to 12 and 45 was non-significant (205.1±17.73 to 246.8±21.72 and 219.7±19.51, p>0.05 (ns) and p>0.05 (ns) in Vedicainals-9 adjuvant group compared to the standard treatment alone (205.1±17.73 to 216.5±22.61 and 179.6±18.09, p>0.05 (ns) and p>0.05 (ns).

11.4.1.2 Secondary efficacy results

11.4.1.2.1 Time to allaying a fever

Table 11-14 a-bThe mean time in days for allaying prolong fever (<7; 5±2 days) and saddleback fever (>7; 12±2 days) in COVID-19 infection

Time in allaying prolonged fever (<7; 5±2 days)						
Mean ± SEM						
Intervention	**Day from (FTP)**	**Days from (AD)**	**Days from (ON)**	**p- value**		
Standard (S)	7.12±1.10	4.12±0.67	6.12±0.66	0.21	0.26	0.21
Vedicinals-9 + Standard (SV9)	5.14±0.79	3.60±0.66	5.42±0.69			

Time in allaying prolonged fever (>7; 12±2 days)

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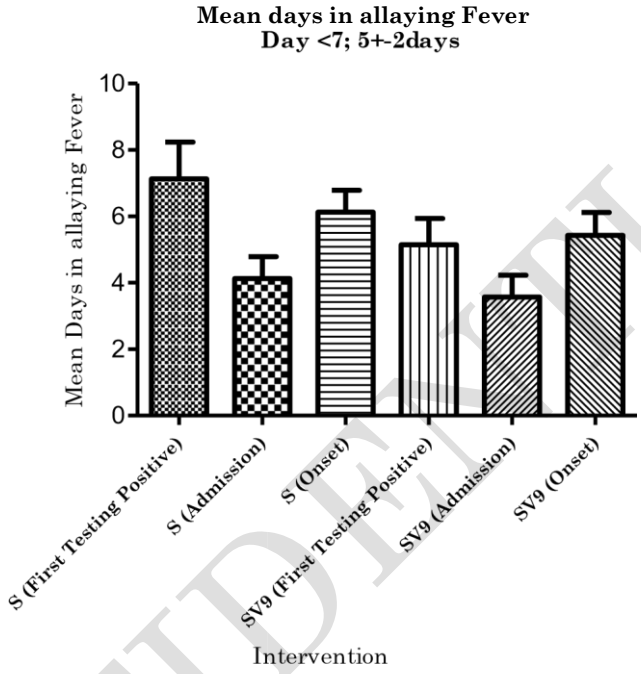
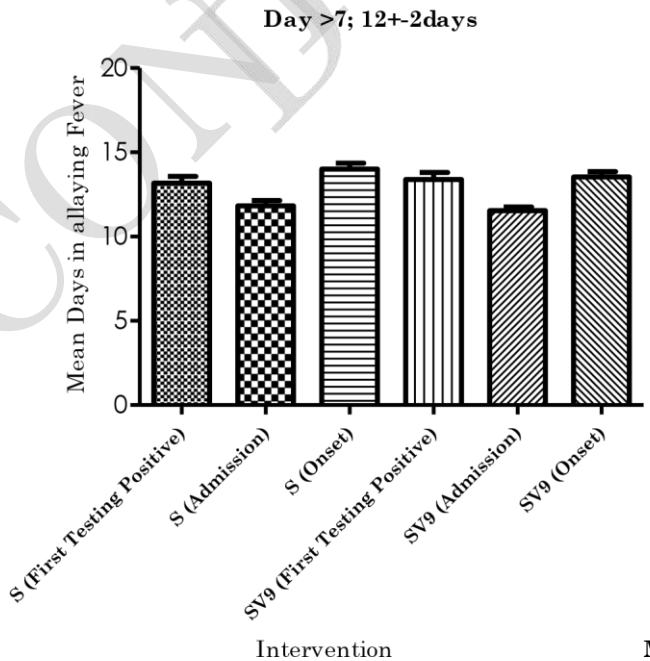
Mean ± SEM						
Intervention	**Day from (FTP)**	**Days from (AD)**	**Days from (ON)**	**p- value**		
Standard (S)	13.17±0.40	11.83±0.30	14.00±0.36	0.10	0.29	0.57
Vedicinals-9 + Standard (SV9)	13.38±0.41	11.54±0.21	13.54±0.31			

Legends: FTP = First testing positive, AD = Admission, ON = Onset





Mean days in allaying Fever

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Fig 11-14 a-bEffect of VEDICINALS-9 on mean time in days for allaying prolong fever (<7; 5±2 days) and saddleback fever (>7; 12±2 days) from first testing positive, onset and admission (*treatment*) in COVID-19 positive patients from day 0 to 5±2and 12±2 days. Data interpret following: comparison of mean time in days for allaying prolong fever from day 0 to day 5±2 and 12±2 days, when vedicinals-9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented mean days (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, when compared before and after intervention at day 5 and 12 in both interventional groups. [Paired t-test].

A total of 124 patients were included in the study; 17.7% (22/124) of cases had prolonged fever, and 15.3% (19/124) had saddleback fever. Out of which 6.4% (08/124) of cases had prolonged fever, and 4.8% (06/142) had saddleback fever in standard group; 11.2% (14/124) of cases had prolonged fever, and 10.5% (13/124) had saddleback fever in vedicinals-9 adjuvant group. The mean time in days for allaying prolong fever (<7; 5±2 days) from first testing positive, onset and admission (*treatment*) were 7.12, 6.12, 4.12 days in standard group compared to 5.14, 5.42 and 3.60 days in vedicinals-9 adjuvant group. Similarly, the mean time in days for allaying saddleback fever (>7; 12±2 days) were 13.16, 14.00, 11.83 days in standard group compared to 13.38, 13.53 and 11.53 days in vedicinals-9 adjuvant group.

The Vedicinals-9 adjuvant group had a mean duration of fever of 3.5 days compared to 4.12 days for prolonged fever cases, while fever recurred at a mean of 11.53 days compared to 11.83 days for those with saddleback fever cases. Both prolonged and saddleback fever were likely to be associated with hypoxia and cases with prolonged fever were also more likely to require ICU admission.

11.4.1.2.2 Arrest or delay in progression in asymptomatic to mild or moderate to severe to critical

Table 11-15 Arrest or delay in progression in asymptomatic to mild; mild to moderate; moderate to severe and severe to critical in COVID-19 infection

Arrest or delay in progression (<5; 12 and 45 days)						
Mean ± SEM						
Intervention	**Fever**	**Cough**	**Fatigue**	**Myalgia**	**S Throat**	**Hypoxia**
Standard (S)	4.12±0.6	5.25±0.4	5.00±0.5	10.29±1.0	10.40±0.5	6.58±2.57
Vedicinals-9 + Standard SV9	3.60±0.6	4.53±0.1	4.44±0.2	07.26±0.7	07.23±0.8	2.57±1.06

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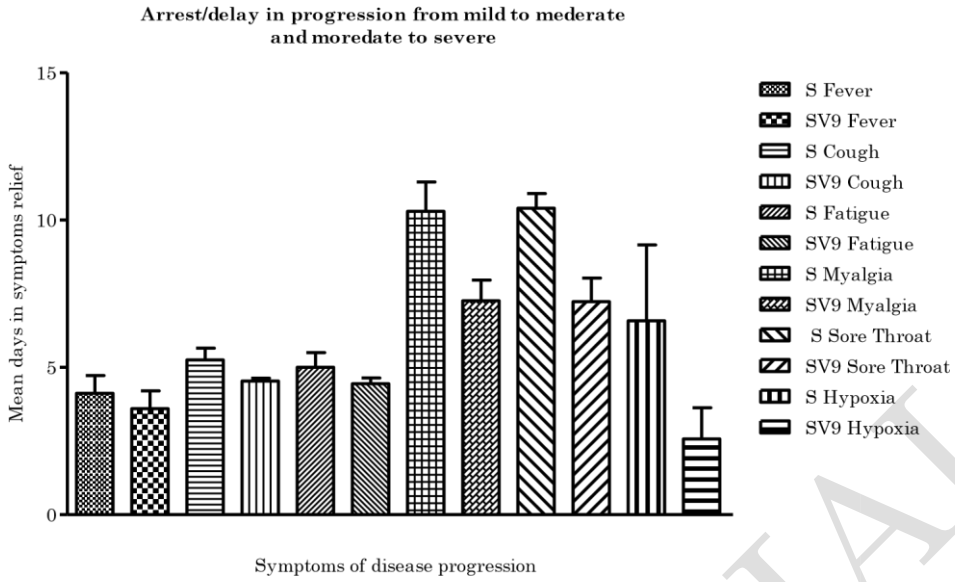

Fig 11-15 Arrest or delay in progression in asymptomatic to mild; mild to moderate; moderate to severe and severe to critical in COVID-19 infection

refer section 11.4.1.2.3.1 to 11.4.1.2.3.5

11.4.1.2.3 Time to symptom relief

11.4.1.2.3.1 Fever

Refer section 11.4.1.2.1.

11.4.1.2.3.2 Cough

Table 11-16 a-bThe mean time in days for allaying cough (<7; 5±2 days) and saddleback cough (>7; 12±2 days) in COVID-19 infection

Time in allaying cough (<7; 5±2 days)						
Mean ± SEM						
Intervention	**Day from (FTP)**	**Days from (AD)**	**Days from (ON)**	**p- value**		
Standard (S)	6.50±0.28	5.25±0.47	5.25±0.47	0.21	0.63	0.63
Vedicinals-9 + Standard (SV9)	5.69±0.32	4.53±0.18	4.53±0.18			

Time in allaying saddleback cough (>7; 5±2 days)				
Mean ± SEM				
Intervention	**Day from (FTP)**	**Days from (AD)**	**Days from (ON)**	**p- value**

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Standard (S)	12.79±0.70	11.57±0.29	11.57±0.29	0.89	0.30	0.30
Vedicinals-9 + Standard (SV9)	13.17±0.44	11.33±0.14	11.33±0.14			

Legends: FTP = First testing positive, AD = Admission, ON = Onset

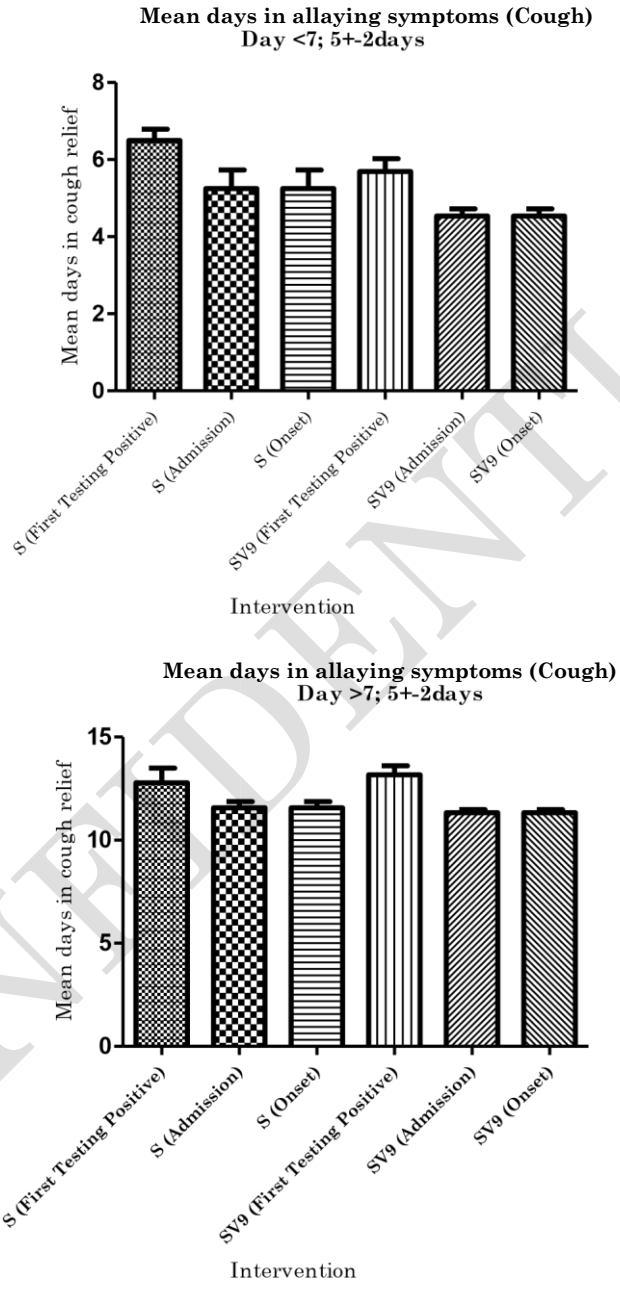

Fig 11-16 a-bEffect of VEDICINALS-9 on mean time in days for allaying cough (<7; 5±2 days) and saddleback cough (>7; 5±2 days) from first testing positive, onset and admission (*treatment*) in COVID-19 positive patients from day 0 to 5±2 and 12±2 days. Data interpret following: comparison of mean time in days for allaying cough and saddleback cough from day 0 to day 5±2 and 12±2 days, when vedicinals-9 (5000mg) adjuvant with standard intervention compared with standard intervention alone. Data represented mean days (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, when compared before and after intervention at day 5 and 12 in both interventional groups. [Paired t-test].

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A total of 124 patients were included in the study; 13.70% (17/124) of cases had cough, and 20.96% (26/124) had saddleback cough. Out of which 3.22% (04/124) of cases had cough, and 11.29% (14/124) had saddleback cough in standard group; 10.48% (13/124) of cases had cough, and 9.67% (12/124) had saddleback cough in vedicinals-9 adjuvant group. The mean time in days for allaying cough (<7; 5±2 days) from first testing positive, onset and admission (*treatment*) were 6.50, 5.25, 5.25 days in standard group compared to 5.69, 4.53and 4.53 days in vedicinals-9 adjuvant group. Similarly, the mean time in days for allaying saddleback cough (>7; 12±2 days) were 12.79, 11.57, 11.57 days in standard group compared to 13.17, 11.33 and 11.33 days in vedicinals-9 adjuvant group.

The Vedicinals-9 adjuvant group had a mean duration of allaying cough of 4.53 days compared to 5.25 days for cough cases, while cough recurred at a mean of 11.33 days compared to 11.57 days for those with saddleback cough cases. Both cough and saddleback cough were likely to be associated with disease progression and pneumonia.

11.4.1.2.3.3 Fatigue

Table 11-17 a-bThe mean time in days for allaying fatigue (<7; 5±2 days) and prolonged fatigue (>7; 12±2 days) in COVID-19 infection

Time in allaying fatigue (<7; 5±2 days)						
Mean ± SEM						
Intervention	**Day from (FTP)**	**Days from (AD)**	**Days from (ON)**	**p- value**		
Standard (S)	9.33±1.20	5.00±0.57	5.00±0.57	0.18	0.18	0.66
Vedicinals-9 + Standard (SV9)	5.78±0.32	4.44±0.24	4.44±0.24			

Time in allaying prolonged fatigue (>7; 12±2 days)						
Mean ± SEM						
Intervention	**Day from (FTP)**	**Days from (AD)**	**Days from (ON)**	**p- value**		
Standard (S)	36.50±5.051	42.13±3.87	41.13±3.78	0.31	0.06	0.07
Vedicinals-9 + Standard (SV9)	25.40±5.45	26.44±5.95	26.00±5.78			

Legends: FTP = First testing positive, AD = Admission, ON = Onset

Mean days in allaying symptoms (Fatigue)

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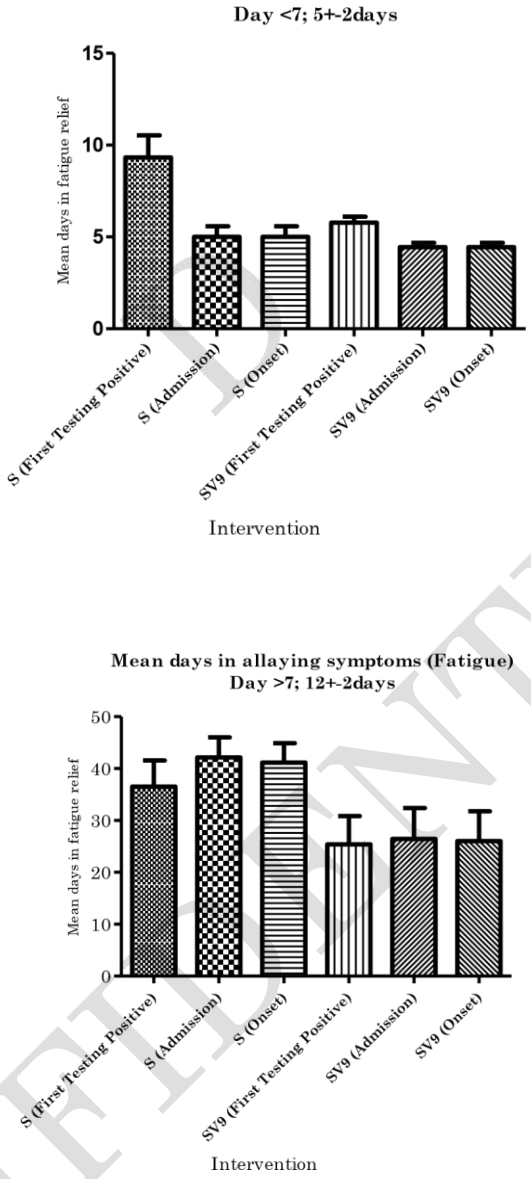

Fig 11-17 a-bEffect of VEDICINALS-9 on mean time in days for allaying fatigue (<7; 5±2 days) and prolonged fatigue (>7; 12±2 days) from first testing positive, onset and admission (*treatment*) in COVID-19 positive patients from day 0 to 5±2, 12±2 and 45±2 days. Data interpret following: comparison of mean time in days for allaying fatigue and prolonged fatigue from day 0 to day 5±2, 12±2 and 45±2 days, when vedicinals-9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented mean days (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, when compared before and after intervention at day 5, 12 and 45 in both interventional groups. [Paired t-test].

A total of 124 patients were included in the study; 08.87% (11/124) of cases had fatigue, and 18.54% (23/124) had prolonged fatigue. Out of which 2.42% (03/124) of cases had fatigue, and 10.48% (13/124) had prolonged fatigue in standard group; 07.25% (9/124) of cases had fatigue, and 08.06% (10/124) had prolonged fatigue in vedicinals-9 adjuvant group. The mean time in days for allaying fatigue (<7; 5±2 days) from first testing positive, onset and admission (*treatment*) were 9.33, 5.00, 5.00 days in standard group compared to 5.78, 4.44and 4.44 days in vedicinals-9 adjuvant group. Similarly, the mean time in days for allaying prolonged fatigue

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(>7; 12±2 and 45±2 days) were 36.50, 41.13, 42.13 days in standard group compared to 25.40, 26.44 and 26.00 days in vedicinals-9 adjuvant group.

The Vedicinals-9 adjuvant group had a mean duration of allaying fatigue of 4.44 days compared to 5.00 days for fatigue cases, while prolonged fatigue at a mean of 26.44 days compared to 42.13 days for those with prolonged fatigue cases. Both fatigue and prolonged fatigue were likely to be associated with disease progression.

11.4.1.2.3.3 Myalgia

Table 11-18 a-bThe mean time in days for allaying myalgia (<12; 12±2 days) and prolonged myalgia (>12; 12±2 days) in COVID-19 infection

Time in allaying myalgia (<12; 12±2 days)						
Mean ± SEM						
Intervention	**Day from (FTP)**	**Days from (AD)**	**Days from (ON)**	**p- value**		
Standard (S)	11.14±1.29	10.29±1.06	9.57±1.11	0.75	0.12	*0.03
Vedicinals-9 + Standard (SV9)	09.00±0.81	7.26±0.73	6.53±0.59			

Time in allaying prolonged myalgia (>12; 12±2 days)						
Mean ± SEM						
Intervention	**Day from (FTP)**	**Days from (AD)**	**Days from (ON)**	**p- value**		
Standard (S)	47.67±0.65	45.25±0.27	45.25±0.27	*0.02	0.49	0.49
Vedicinals-9 + Standard (SV9)	45.25±0.75	44.75±0.47	44.75±0.47			

Legends: FTP = First testing positive, AD = Admission, ON = Onset

Mean days in allaying symptoms(Myalgia)

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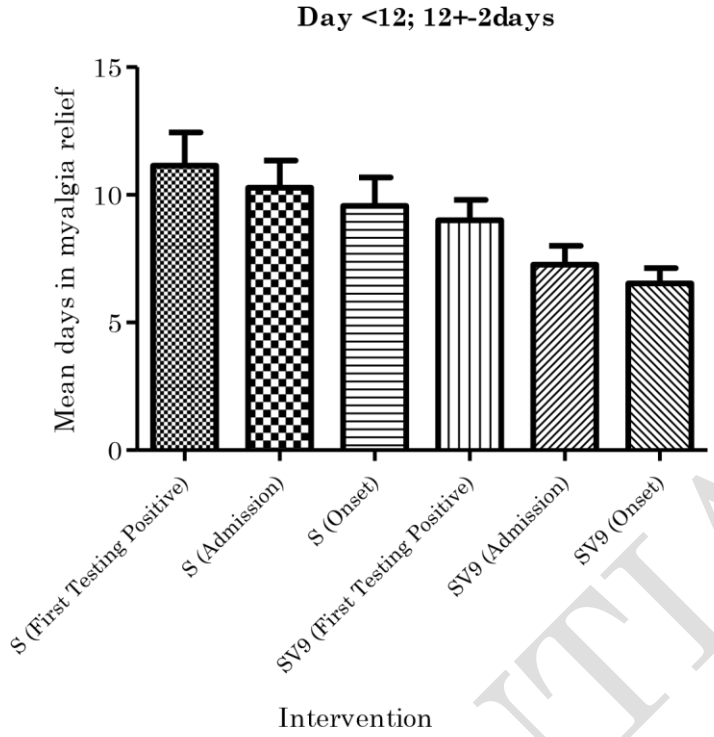

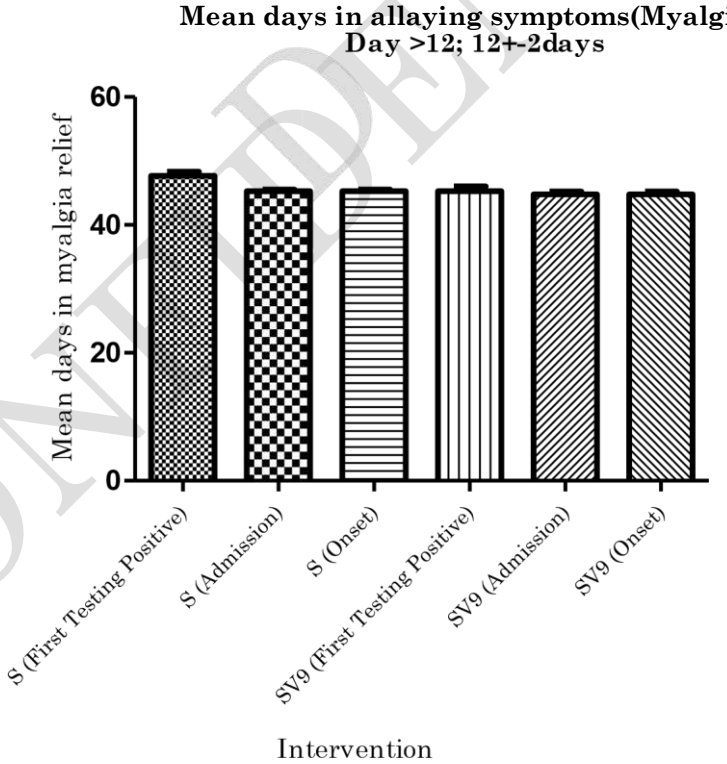

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Fig 11-18 a-bEffect of VEDICINALS-9 on mean time in days for allaying myalgia (<12; 5±2 days) and prolonged myalgia (>12; 12±2 and 45±2 days) from first testing positive, onset and admission (*treatment*) in COVID-19 positive patients from day 0 to 5±2, 12±2 and 45±2 days. Data interpret following: comparison of mean time in days for allaying myalgia and prolonged myalgia from day 0 to day 5±2, 12±2 and 45±2, when vedicinals-9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented mean days (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, when compared before and after intervention at day 5, 12 and 45 in both interventional groups. [Paired t-test].

A total of 124 patients were included in the study; 17.74% (22/124) of cases had myalgia, and 12.90% (16/124) had prolonged myalgia. Out of which 5.64% (07/124) of cases had myalgia, and 09.67% (12/124) had prolonged myalgia in standard group; 12.09% (15/124) of cases had myalgia, and 3.22% (4/124) had prolonged myalgia in vedicinals-9 adjuvant group. The mean time in days for allaying myalgia (<12; 12±2 days) from first testing positive, onset and admission (*treatment*) were 11.14, 9.57, 10.29 days in standard group compared to 9.00, 6.53 and 7.26 days in vedicinals-9 adjuvant group. Similarly, the mean time in days for allaying prolonged myalgia (>12; 12±2 days) were 47.67, 45.25, 45.25 days in standard group compared to 45.25, 44.75 and 44.75 days in vedicinals-9 adjuvant group.

The Vedicinals-9 adjuvant group had a mean duration of allaying myalgia of 7.26 days compared to 10.29 days for myalgia cases, while prolonged myalgia at a mean of 44.75 days compared to 45.25 days for those with prolonged myalgia cases. Both myalgia and prolonged myalgia were likely to be associated with disease progression.

11.4.1.2.3.4 Sore Throat

Table 11-19 a-b The mean time in days for allaying sore throat (<12; 5±2 days) and prolonged sore throat (>12; 12±2 days) in COVID-19 infection

Time in allaying sore throat (<12; 12±2 days)						
Mean ± SEM						
Intervention	**Day from (FTP)**	**Days from (AD)**	**Days from (ON)**	**p- value**		
Standard (S)	11.47±0.32	10.40±0.58	10.40±0.58	0.001 **	0.009 **	0.009 **
Vedicinals-9 + Standard (SV9)	8.15±0.70	07.23±0.87	7.23±0.87			

Time in allaying prolonged sore throat (>12; 12±2 days)						
Mean ± SEM						
Intervention	**Day from (FTP)**	**Days from (AD)**	**Days from (ON)**	**p- value**		
Standard (S)	45.00±1.00	44.67±0.66	44.67±0.66	0.03 *	0.01 *	0.01 *
Vedicinals-9 + Standard (SV9)	10.33±5.23	08.33±4.17	08.33±4.17			

Legends: FTP = First testing positive, AD = Admission, ON = Onset

Mean days in allaying symptoms (Sore throat)
Day <12; 12+-2days

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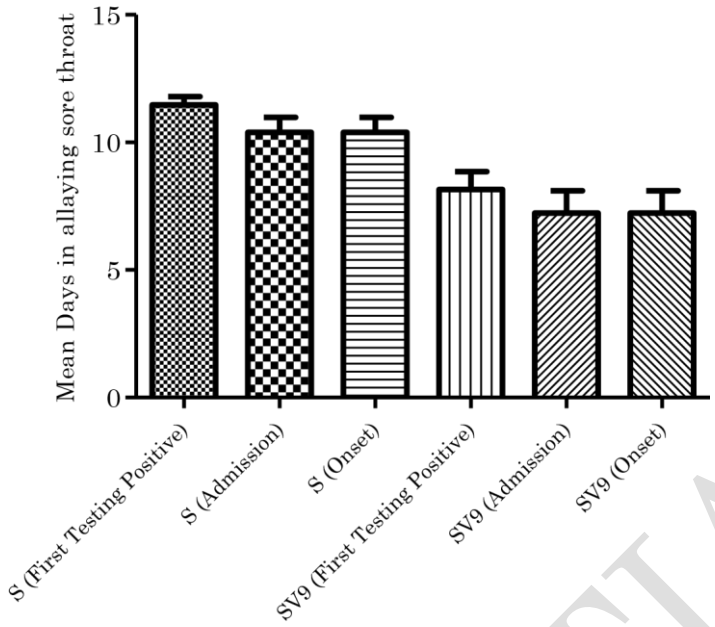

Mean days in allaying symptoms (Sore throat)
Day >12; 12+-2days

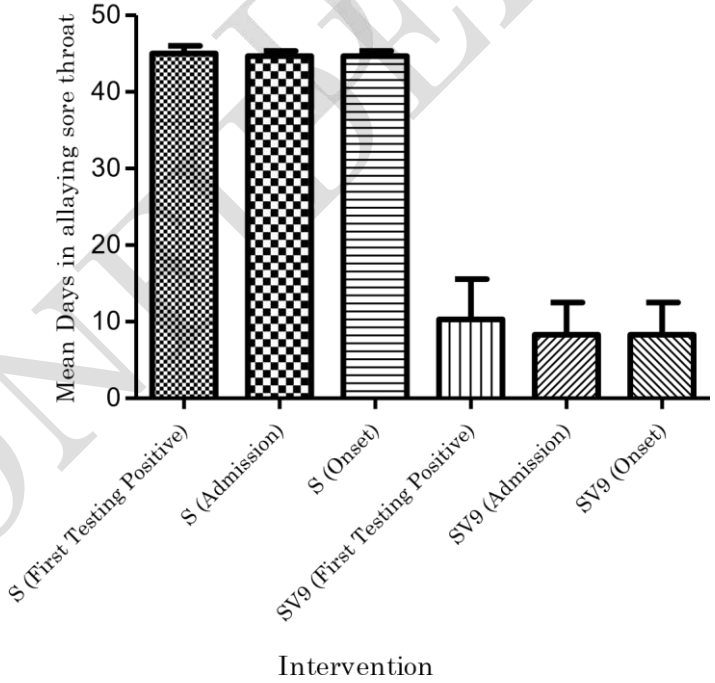

Fig 11-19 a-bEffect of VEDICINALS-9 on mean time in days for allaying sore throat (<12; 5±2 days) and prolonged sore throat (>12; 12±2 and 45±2 days) from first testing positive, onset and admission (*treatment*) in COVID-19 positive patients from day 0 to 5±2, 12±2 and 45±2 days. Data interpret following: comparison of mean time in days for allaying sore throat and prolonged sore throat from day 0 to day 5±2, 12±2 and 45±2, when vedicinals-9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented mean days (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 5, 12 and 45 in both interventional groups. [Paired t-test].

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A total of 124 patients were included in the study; 22.58% (28/124) of cases had sore throat, and 4.03% (5/124) had prolonged sore throat. Out of which 12.09% (15/124) of cases had sore throat, and 2.41% (03/124) had prolonged sore throat in standard group; 10.48% (13/124) of cases sore throat, and 1.61% (02/124) had prolonged sore throat in vedicinals-9 adjuvant group. The mean time in days for allaying sore throat(<12; 12±2 days) from first testing positive, onset and admission (*treatment*) were 11.47, 10.40, 10.40 days in standard group compared to 8.15, 7.23 and 7.23 days in vedicinals-9 adjuvant group. Similarly, the mean time in days for allaying prolonged sore throat (>12; 12±2 days) were 45.00, 44.67, 44.67 days in standard group compared to 10.33, 8.33 and 8.33 days in vedicinals-9 adjuvant group.

The Vedicinals-9 adjuvant group had a mean duration of allaying sore throat*of 7.23 days compared to 10.40 days for* sore throat *cases, while* prolonged sore throat *at a mean of 08.33 days compared to 44.67 days for those with* prolonged sore throat *cases. Both* sore throat *and* prolonged sore throat *were likely to be associated with disease progression.*

11.4.1.2.3.5 Hypoxia (SpO_2) and dyspnea

Table 11-20 a-b The mean time in days for allaying mild-moderate hypoxia (SpO_2>90-94) and severe hypoxia (SpO_2<90) in COVID-19 infection

Time in allaying mild-moderate hypoxia (SpO_2>90-94)						
Mean ± SEM						
Intervention	**Day from (FTP)**	**Days from (AD)**	**Days from (ON)**	**p- value**		
Standard (S)	6.94±2.53	6.58±2.57	7.64±2.56	0.61	0.35	0.35
Vedicinals-9 + Standard (SV9)	4.75±0.94	2.57±1.06	5.50±1.00			

Time in allaying severe hypoxia (SpO_2<90)						
Mean ± SEM						
Intervention	**Day from (FTP)**	**Days from (AD)**	**Days from (ON)**	**p- value**		
Standard (S)	6.77±2.39	6.44±2.42	7.50±2.41	0.18	0.08	0.10
Vedicinals-9 + Standard (SV9)	6.14±1.26	6.00±1.29	7.00±1.29			

Legends: FTP = First testing positive, AD = Admission, ON = Onset

Mean days in allaying symptoms (Hypoxia)

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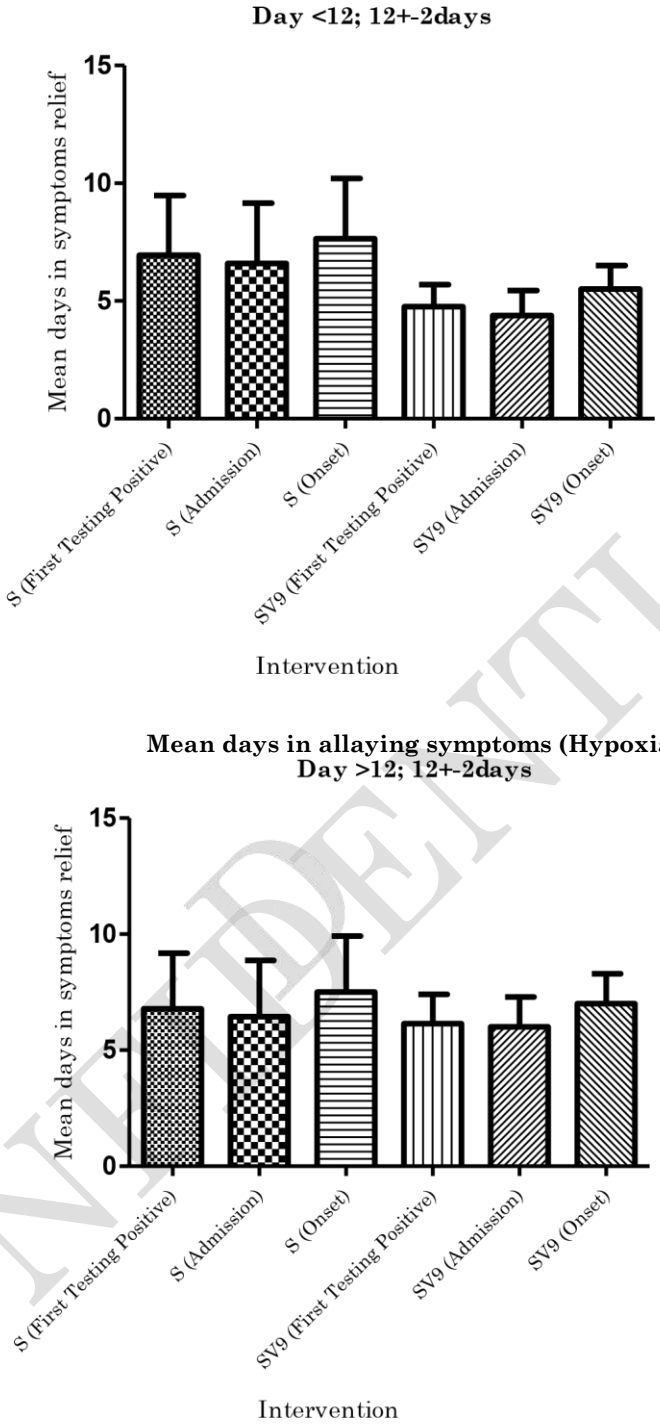

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Fig 11-20 a-bEffect of VEDICINALS-9 on mean time in days for allaying for allaying mildmoderate hypoxia (SpO2>90-94) and severe hypoxia (SpO2<90) from first testing positive, onset and admission (*treatment*) in COVID-19 positive patients from day 0 to 5±2, 12±2 and 45±2 days. Data interpret following: comparison of mean time in days allaying mild-moderate hypoxia (SpO_2>90-94) and severe hypoxia (SpO_2<90) from day 0 to day 5±2, 12±2 and 45±2, when vedicinals-9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented mean days (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, when compared before and after intervention at day 5, 12 and 45 in both interventional groups. [Paired t-test].

A total of 124 patients were included in the study; 20.16% (25/124) of cases had mild-moderate hypoxia, and 20.16% (25/124) had severe hypoxia (SpO_2<90). Out

of which 13.70% (17/124) of cases had mild-moderate hypoxia (SpO_2<90), and 14.51% (18/124) had severe hypoxia (SpO_2<90) in standard group; 6.45% (8/124) of cases had mild-moderate hypoxia, and 5.64% (7/124) had severe hypoxia (SpO_2<90) in vedicinals-9 adjuvant group. The mean time in days for allaying mild-moderate hypoxia (SpO_2>90-94) from first testing positive, onset and admission (*treatment*) were 6.94, 7.64, 6.58 days in standard group compared to 4.75, 5.50 and 2.57 days in vedicinals-9 adjuvant group. Similarly, the mean time in days for allaying severe hypoxia (SpO_2<90) were 6.77, 7.50, 6.44 days in standard group compared to 6.14, 7.00 and 6.00 days in vedicinals-9 adjuvant group.

The Vedicinals-9 adjuvant group had a mean duration of allaying mild-moderate hypoxia (SpO_2>90-94) *of 2.57 days compared to 6.58 days for mild to moderate hypoxia cases, while* severe hypoxia (SpO_2<90) *at a mean of 6.00 days compared to 6.44 days for those with prolonged fatigue cases. Both mild-moderate and severe hypoxia were likely to be associated with disease progression and admission to ICU.*

11.4.1.2.4 Days of treatment and Hospitalization

Table 11-21Days of hospitalization and percentage of patients discharged/turning negative

Days of hospitalization			
Intervention	**Percentage (%)**		
	Day (4 to 7)	**Day (8 to 12)**	**Day (<12-14)**
Standard (S)	37.09	43.54	19.35
Vedicinals9 + Standard (SV9)	58.06	29.03	12.90

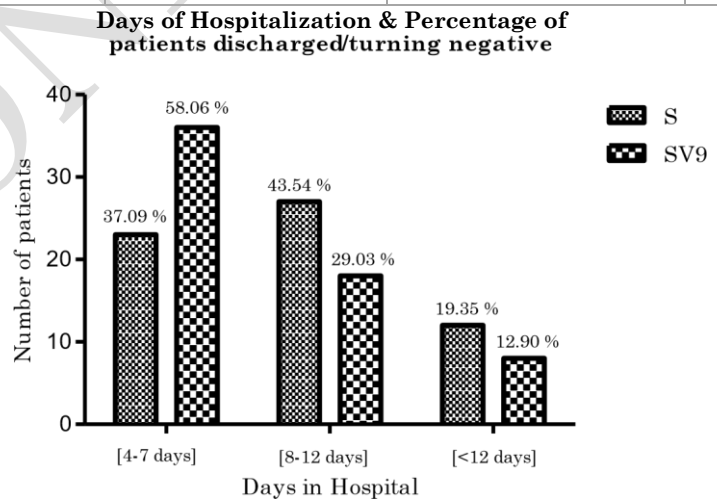

Fig 11-21Effect of VEDICINALS-9 on mean time in days to remain hospitalized with subsequent discharge from first testing positive until tested negative or discharged. Data interpret following: comparison of mean time in days and percentage of patients hospitalized when vedicinals-9 5000

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mg adjuvant with standard intervention compared with standard intervention alone. Data represented days and percentage of patients (%) in two comparable interventional group (n=62 per group).

The mean time in days to remain hospitalized with subsequent discharge was 4 to 6.5 days for 37.09% (23/62) of COVID-19 patients in standard group compared to 58.06% (36/62) days in vedicinals-9 adjuvant group. Similarly, the mean time in days for 43.54% (27/62) of COVID-19 patients in standard group compared to 29.03% (18/62) days in vedicinals-9 adjuvant group was 7 to 12 days. Those with mean time in days <12 days were 19.35% (12/62) in standard group compared to 12.90% (08/62) in vedicinals-9 adjuvant group.

The Vedicinals-9 adjuvant group had more than 58 % patients discharged from hospital in first 4 to 7 days of testing positive compared to the 37 % standard treatment group.

11.4.1.2.5 Incidence of respiratory failure and requirement of rescue medication

No incidence of respiratory failure and rescues medication observed in entire trial duration (*Observation and Follow up period*)

11.4.1.2.6 Percent Mortality

No mortality observed in entire trial duration (*Observation and Follow up period*)

11.4.1.3 Exploratory efficacy results

Not applicable.

11.4.2 Statistical and analytical issues

Not applicable.

11.4.3 Tabulation of individual response data

Individual patient data generated for all patients are provided in Appendix 16.2.6.

11.4.4 Drug dose, drug concentration and relationships to response

Not applicable

11.4.5 Drug-drug and drug-disease interactions

Not applicable

11.4.6 By-patient displays

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Not applicable

11.4.7 Summary of efficacy results

The various measurements at each study visit thatwere randomized to standard and standard+Vedicinals-9, can be found in Table 11-1 to Table 11-21.

12 SAFETY EVALUATION

12.1 EXTENT OF EXPOSURE

12.1.1 Dosage

The planned doses in the study were:

The study was divided into 2 sequential phases for a total of 5 visits:

Phase I: Screening/Eligibility phase
Phase II: Treatment Phase

Patients were assigned at Visit 2 (Eligibility) to one of the following two treatment arms in a ratio of 1:1:

- Arm 1: Standard Treatment (dosed in the morning and in the evening)
- Arm 2: Standard Treatment + Vedicinals-9 (dosed in the morning, afternoon and in the evening)

12.1.2 Patient exposure

12.1.3 Concomitant medication

No concomitant medications data were reported for the other patients.

12.2 ADVERSE EVENTS

12.2.1 Summary of adverse events

No AE recorded. No summary listed.

12.2.2 Display of adverse events

One non-serious event (Headache) was reported by the one patient who was randomized to standard treatment(Appendix 16.3.1).

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12.2.3 Analysis of adverse events

The reported event of headache was mild in severity and was not related to the study medication (Appendix 16.3.1).

12.2.4 Listing of adverse events by patient

No AE listing was generated as there was only one non-serious event headache reported.

12.3 DEATHS, OTHER SERIOUS ADVERSE EVENTS AND OTHER SIGNIFICANT ADVERSE EVENTS

There were no deaths, serious adverse events and other significant adverse events reported in the study. Therefore, no listings were generated, and no narratives were required.

12.3.1 Listing of Deaths, other Serious Adverse Events and Other Significant Adverse Events

12.3.1.1 Deaths

No death reported.

12.3.1.2 Other Serious Adverse Events

No death reported.

12.3.1.3 Other Significant Adverse Events

No death reported.

12.3.2 Narratives of Deaths, Other Serious Adverse Events and Certain other Significant Adverse Events

Not applicable

12.3.3 Analysis and Discussion of Deaths, Other Serious Adverse Events and Other Significant Adverse Events

Not applicable

12.4 CLINICAL LABORATORY EVALUATION

Laboratory evaluations (hematology, clinical chemistry and urinalysis) were performed in this study and individual patient data represented in Appendix 16.4.

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12.4.1 Hematological assessments – CBC and ESR

Table 12-1 Change in baseline value of Hemoglobin

Hemoglobin (gm/dL)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	13.79±0.21	13.27±0.20	14.03±0.14	**P (0.0089)	ns (0.0856)
Vedicinals9 + Standard (SV9)	13.13±0.23	13.50±0.17	13.76±0.13	ns (0.1010)	**P (0.0055)

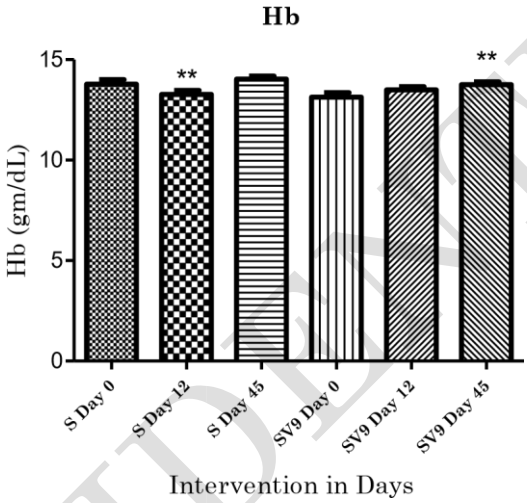

Fig 12-1 Change in Hb levels (gm/dL) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of Hb levels (gm/dL) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of Hb (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 12 and day 45 in both interventional groups [Paired t-test].

Table 12-2 Change in baseline value of RBC

RBC (x 10^{12}/L)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	4.80±0.08	4.63±0.06	4.83±0.03	ns (0.0561)	ns (0.8731)
Vedicinals9 + Standard (SV9)	4.59±0.07	4.73±0.05	4.77±0.04	ns (0.0790)	**P (0.0070)

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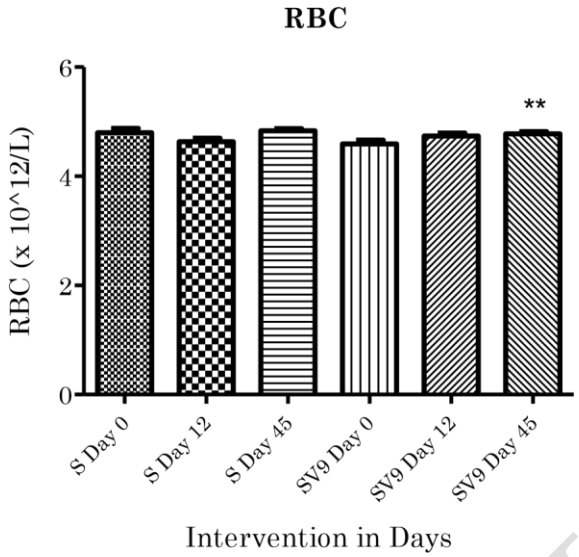
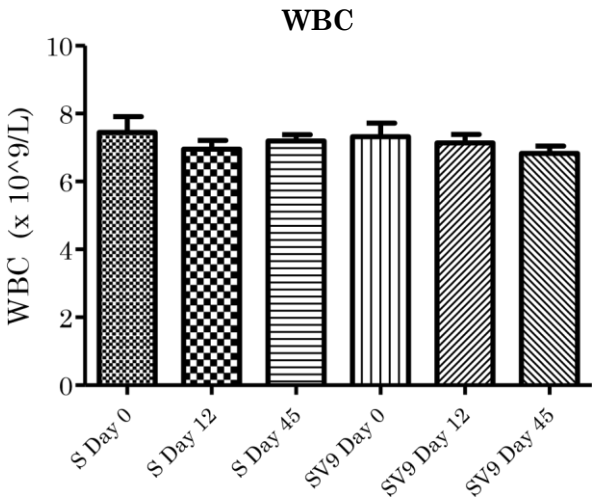


Fig 12-2 Change in RBC levels (x 10^{12}/L) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of RBC levels (x 10^{12}/L) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of RBC (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 12 and day 45 in both interventional groups [Paired t-test].

Table 12-3Change in baseline value of WBC

WBC (x 10^9/L)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	7.45±0.46	6.95±0.25	7.19±0.18	ns (0.2668)	ns (0.5987)
Vedicinals9 + Standard (SV9)	7.32±0.39	7.13±0.25	6.82±0.22	ns (0.5042)	ns (0.2747)



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Intervention in Days

Fig 12-3 Change in WBC levels (x 10^9/L) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of WBC levels (x 10^9/L) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of WBC (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 12 and day 45 in both interventional groups [Paired t-test].

Table 12-4 Change in baseline value of Platelets

Platelets (x 10^9/L)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	246.00±10.75	241.00±10.75	304.9±13.51	ns (0.7401)	***P (0.0002)
Vedicinals9 + Standard (SV9)	231.90±13.51	244.80± 10.49	291.5±9.52	ns (0.3437)	****P (<0.0001)

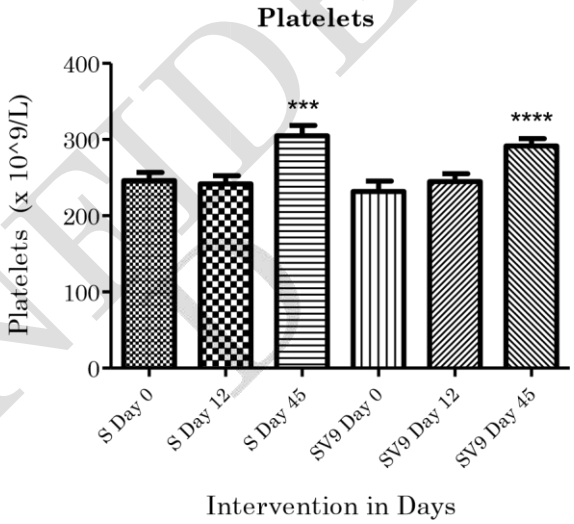

Fig 12-4 Change in Platelets levels (x 10^9/L) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of Platelets levels (x 10^9/L) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of Platelets (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 12 and day 45 in both interventional groups [Paired t-test].

Table 12-5 Change in baseline value of Hematocrit

Hematocrit (%)

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Intervention	Mean ± SEM			*p*- value	
	Day 0	Day 12	Day 45	Day 0 Vs 12	Day 0 Vs 45
Standard (S)	41.59±0.55	40.15±0.52	44.41±0.52	**P (0.0094)	***P (0.0002)
Vedicinals9 + Standard (SV9)	40.16±0.64	41.47±0.44	44.75±0.98	*P (0.0218)	***P (0.0002)

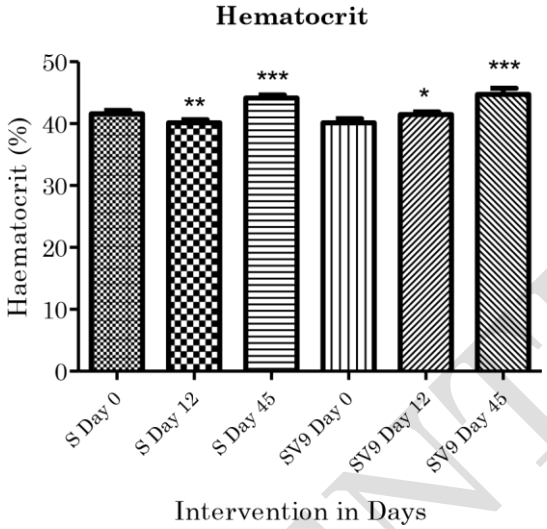

Fig 12-5 Change in Hematocrit levels (%) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of Hematocrit levels (%) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of Hematocrit (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 12 and day 45 in both interventional groups [Paired t-test].

Table 12-6 Change in baseline value of Neutrophil

Neutrophil (%)					
Intervention	Mean ± SEM			*p*- value	
	Day 0	Day 12	Day 45	Day 0 Vs 12	Day 0 Vs 45
Standard (S)	63.20±1.62	58.17±1.27	58.97±0.73	*P (0.0122)	*P (0.0113)
Vedicinals9 + Standard (SV9)	62.92±1.61	57.75±1.33	57.93±0.73	**P (0.0059)	***P (0.0007)

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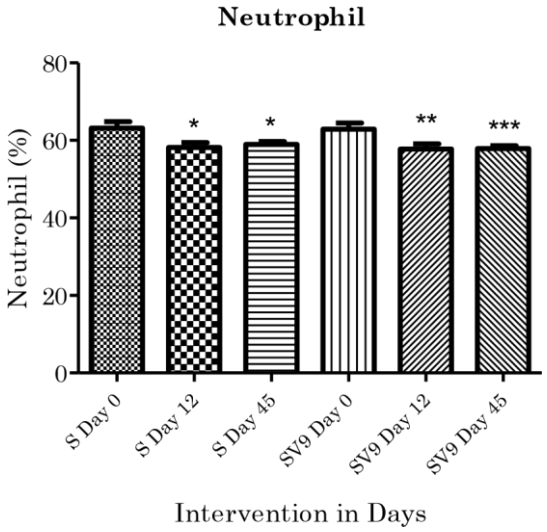

Fig 12-6 Change in Neutrophil levels (%) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of Hematocrit levels (%) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of Hematocrit (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 12 and day 45 in both interventional groups [Paired t-test].

Table 12-7 Change in baseline value of Eosinophil

Eosinophil (%)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	2.10±0.19	3.10±0.18	4.63±0.20	***P (0.0004)	****P (<0.0001)
Vedicinals9 + Standard (SV9)	2.46±0.19	3.21±0.20	4.03±0.19	**P (0.0020)	****P (<0.0001)

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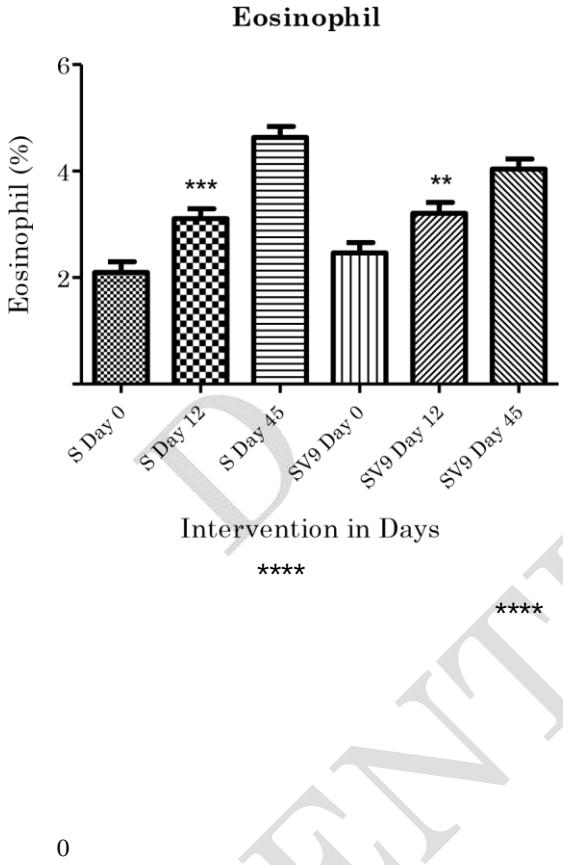

Fig 12-7 Change in Eosinophil levels (%) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of Eosinophil levels (%) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of Eosinophil (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 12 and day 45 in both interventional groups [Paired t-test].

Table 12-8 Change in baseline value of Lymphocyte

Lymphocyte (%)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	30.63±1.60	31.93±1.03	30.93±0.60	ns (0.4995)	ns (0.9469)
Vedicinals9 + Standard (SV9)	31.32±1.52	31.27±0.96	30.65±0.58	ns (0.9872)	ns (0.9321)

Lymphocyte

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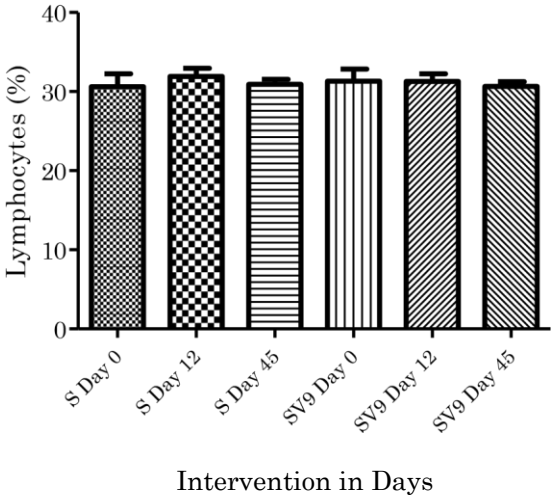

Fig 12-8 Change in Lymphocyte levels (%) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of Lymphocyte levels (%) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of Lymphocyte (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 12 and day 45 in both interventional groups [Paired t-test].

Table 12-9 Change in baseline value of Monocyte

Monocyte (%)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	4.87±0.37	4.74±0.33	3.30±0.11	ns (0.7411)	****P (<0.0001)
Vedicinals9 + Standard (SV9)	3.97±0.32	3.73±0.30	2.86±0.11	ns (0.3468)	****P (<0.0001)

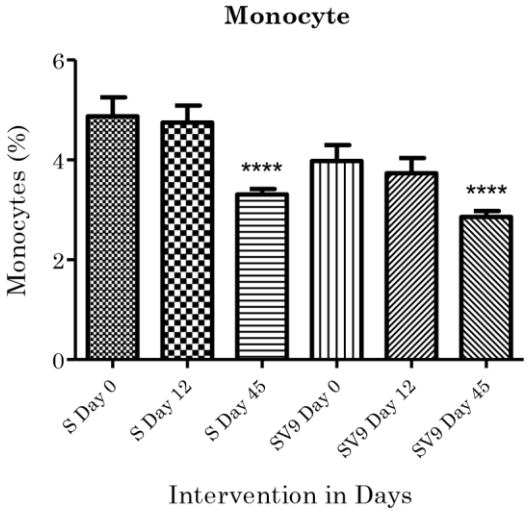

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Fig 12-9 Change in Monocyte levels (%) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of monocyte levels (%) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of monocyte (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 12 and day 45 in both interventional groups [Paired t-test].

Table 12-10 Change in baseline value of Basophil

Basophil (%)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	0.24±0.03	0.35±0.07	0.00±0.00	ns (0.1755)	****P (<0.0001)
Vedicinals9 + Standard (SV9)	0.12±0.21	0.30±0.07	0.28±0.28	*P (0.0196)	ns (0.5791)

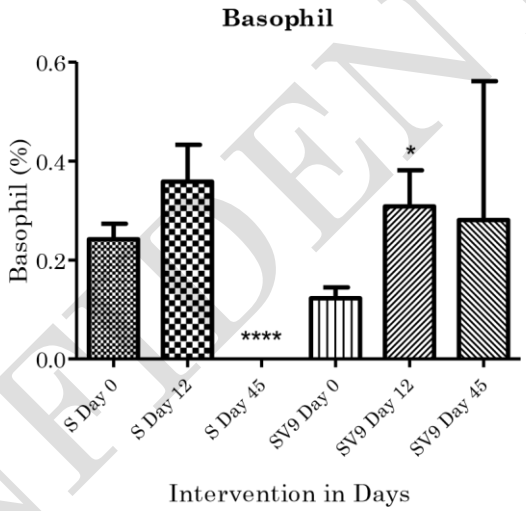

Fig 12-10 Change in Basophil levels (%) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of basophil levels (%) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of basophil (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 12 and day 45 in both interventional groups [Paired t-test].

Table 12-11 Change in baseline value of ESR

ESR (mm/hr)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**

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Standard (S)	16.85±1.31	14.32±1.19	6.24±0.77	ns (0.1087)	****P (<0.0001)
Vedicinals9 + Standard (SV9)	19.65±1.36	13.28±0.88	6.51±0.52	****P (<0.0001)	****P (<0.0001)

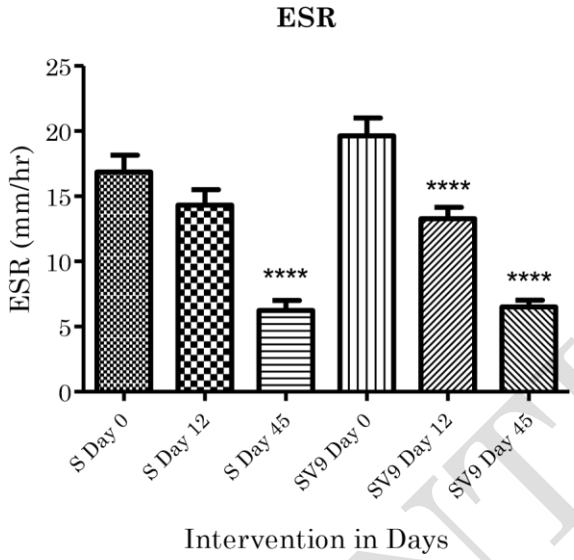

Fig 12-11 Change in ESR levels (mm/hr) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of ESR levels (mm/hr) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of ESR (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 12 and day 45 in both interventional groups [Paired t-test].

12.4.2 Biochemical Assessments – Liver Function Tests, Renal Function Tests, Lipid Profile and Fasting Blood Sugar

12.4.2.1 Liver Function Tests – ALT, AST, ALP, Bilirubin

Table 12-12 Change in baseline value of ALT/SGPT

ALT/SGPT (U/L)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	51.74±2.09	40.11±1.27	36.93±1.11	****P (<0.0001)	****P (<0.0001)
Vedicinals9 + Standard (SV9)	48.91±2.29	41.35±2.06	38.48±1.81	***P(0.0009)	***P (0.0001)

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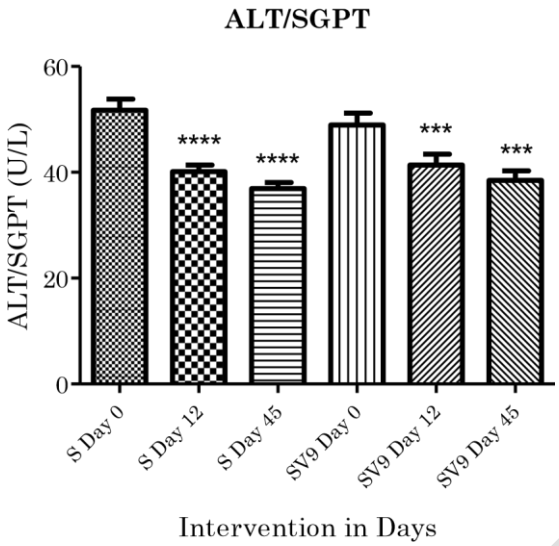

Fig 12-12 Change in ALT levels (U/L) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of ALT levels (U/L) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of ALT (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 12 and day 45 in both interventional groups [Paired t-test].

Table 12-13 Change in baseline value of AST/SGOT

AST/SGOT (U/L)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	49.64±1.85	41.44±1.47	38.66±1.11	***P (0.0002)	****P (<0.0001)
Vedicinals9 + Standard (SV9)	45.57±1.73	39.84±1.45	39.17±0.96	**P (0.0059)	***P (0.0006)

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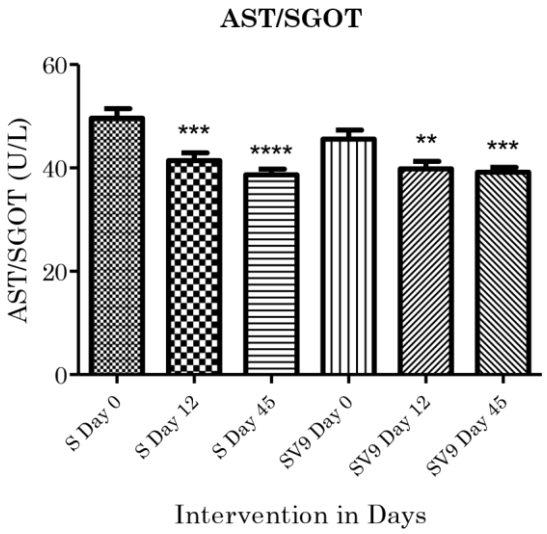

Fig 12-13 Change in AST levels (U/L) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of AST levels (U/L) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of AST (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 12 and day 45 in both interventional groups [Paired t-test].

Table 12-14 Change in baseline value of ALP

ALP (U/L)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	103.8±5.23	112.2±3.86	100.6±2.93	*P (0.0349)	ns (0.5455)
Vedicinals9 + Standard (SV9)	101.6±4.49	109.3±3.59	97.82±3.21	ns (0.0607)	ns (5091)

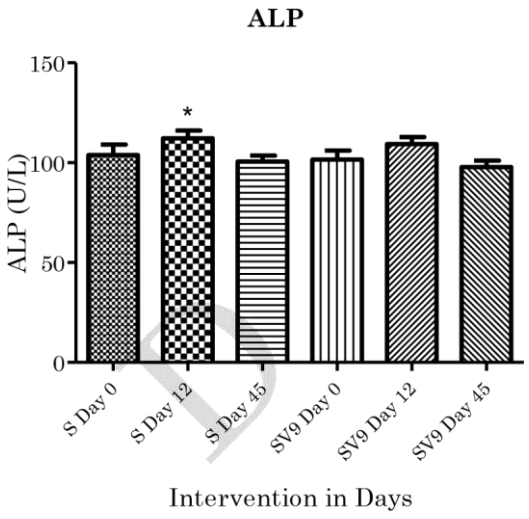

Fig 12-14 Change in ALP levels (U/L) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of ALP levels (U/L) from day 0 to day 45, when vedicinals9 5000mg

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adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of ALP (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 12 and day 45 in both interventional groups [Paired t-test].

Table 12-15 Change in baseline value of Bilirubin

Bilirubin (mg/dL)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	0.71±0.03	0.58±0.02	0.70±0.02	***P (0.0003)	ns (0.6108)
Vedicinals9 + Standard (SV9)	0.68±0.07	0.59±0.02	0.65±0.02	ns (0.1916)	ns (0.6458)

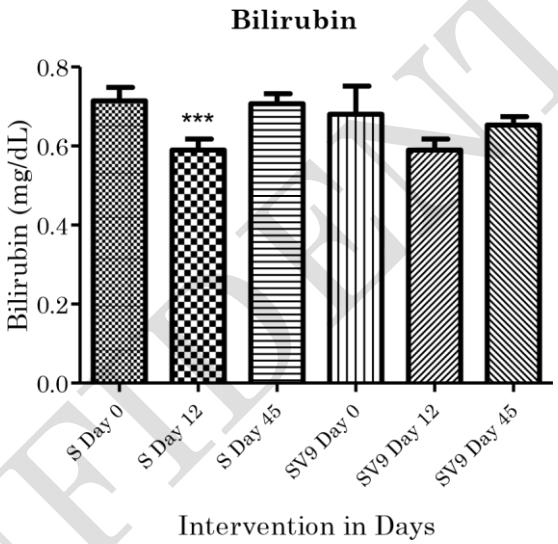

Fig 12-15 Change in Bilirubin levels (mg/dL) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of bilirubin levels (mg/dL) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of bilirubin (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 12 and day 45 in both interventional groups [Paired t-test].

12.4.2.2 Renal Function Tests – BUN and Creatinine

Table 12-16 Change in baseline value of BUN

BUN (mg/dL)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	13.65±0.34	13.94±0.38	14.31±0.37	ns (0.4930)	ns (0.0861)

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Vedicinals9 + Standard (SV9)	13.03±0.37	13.19±0.32	13.49±0.39	ns (0.6859)	ns (0.4488)

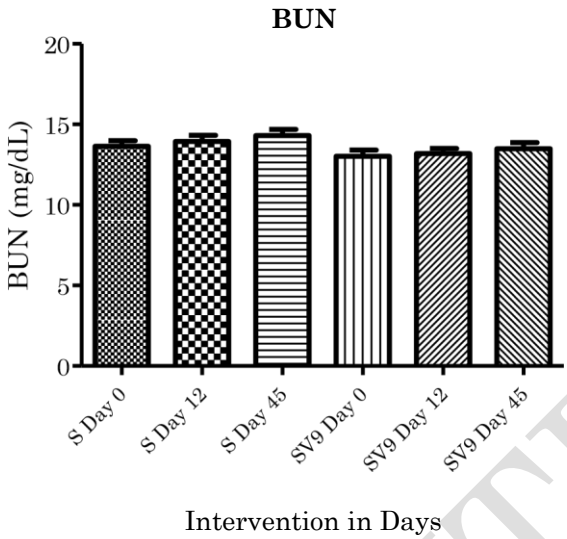

Fig 12-16 Change in BUN levels (mg/dL) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of BUN levels (mg/dL) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of BUN (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 12 and day 45 in both interventional groups [Paired t-test].

Table 12-17 Change in baseline value of Creatinine

Creatinine (mg/dL)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	0.74±0.02	0.65±0.03	0.92±0.02	*P (0.0301)	****P (<0.0001)
Vedicinals9 + Standard (SV9)	0.71±0.02	0.72±0.02	0.89±0.06	ns (0.7458)	*P (0.0125)

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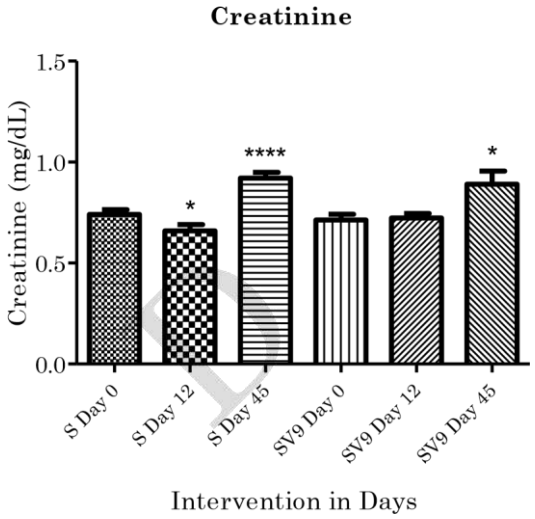
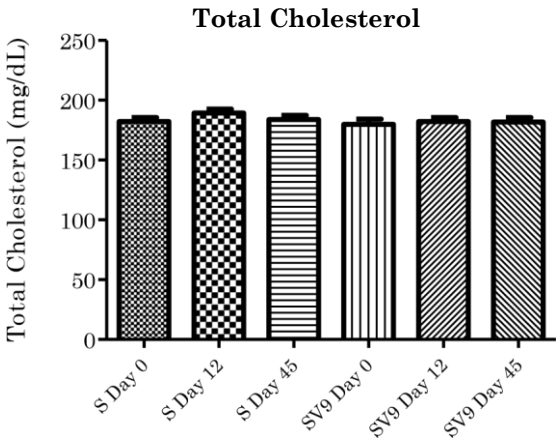


Fig 12-17 Change in creatinine levels (mg/dL) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of creatininelevels (mg/dL) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of creatinine(Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 12 and day 45 in both interventional groups [Paired t-test].

12.4.2.3 Lipid Profile – Total Cholesterol, HDL Cholesterol, LDL Cholesterol, VLDL and Triglycerides

Table 12-18 Change in baseline value of Total Cholesterol

Total Cholesterol (mg/dL)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	182.2±3.28	189.3±3.40	183.9±3.46	ns (0.0583)	ns (0.7456)
Vedicinals9 + Standard (SV9)	179.9±4.48	182.2±3.24	181.8±3.80	ns (0.7080)	ns (0.9411)



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Intervention in Days

Fig 12-18 Change in total cholesterol levels (mg/dL) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of total cholesterollevels (mg/dL) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of total cholesterol(Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 12 and day 45 in both interventional groups [Paired t-test].

Table 12-19 Change in baseline value of HDL Cholesterol

HDL Cholesterol (mg/dL)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	40.12±0.79	41.01±0-61	46.18±1.10	ns (0.1475)	****P (<0.0001)
Vedicinals9 + Standard (SV9)	45.47±2.57	42.12±0.67	47.17±0.65	ns (0.2023)	ns (0.6078)

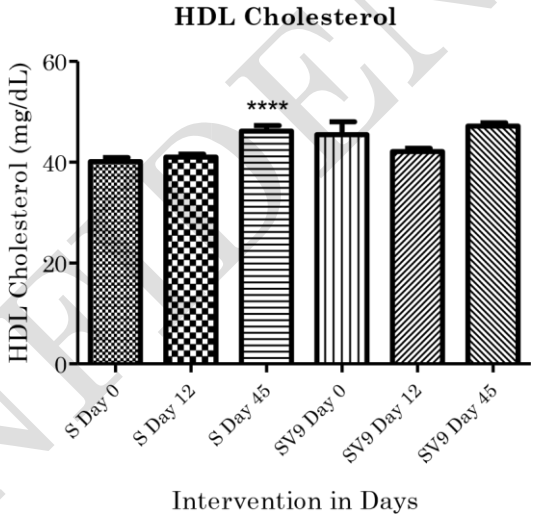

Fig 12-19 Change in HDL cholesterollevels (mg/dL) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of HDL cholesterollevels (mg/dL) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of HDL cholesterol(Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 12 and day 45 in both interventional groups [Paired t-test].

Table 12-20 Change in baseline value of LDL Cholesterol

LDL Cholesterol (mg/dL)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**

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Standard (S)	112.6±3.83	114.6 ±3.51	108.0±4.18	ns (0.5443)	ns (0.5404)
Vedicinals9 + Standard (SV9)	104.1±4.23	106.6±3.67	99.68±4.04	ns (0.4961)	ns (0.3549)

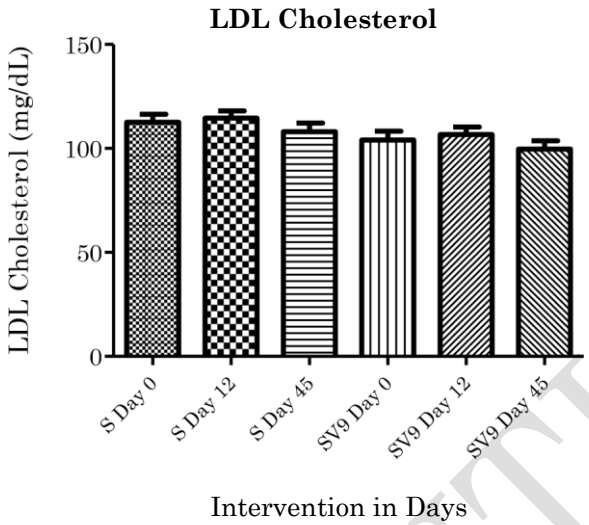

Fig 12-20 Change in LDL cholesterollevels (mg/dL) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of LDL cholesterollevels (mg/dL) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of LDL cholesterol(Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 12 and day 45 in both interventional groups [Paired t-test].

Table 12-21 Change in baseline value of VLDL Cholesterol

VLDL (mg/dL)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	28.66±2.26	29.89±2.74	29.05±1.02	ns (0.4953)	ns (0.8720)
Vedicinals9 + Standard (SV9)	30.28±2.09	28.87±7.70	31.87±0.88	ns (0.1070)	ns (0.7719)

VLDL

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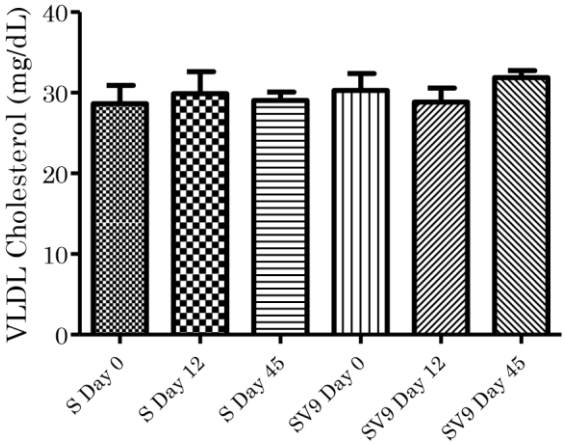

Fig 12-21 Change in VLDL levels (mg/dL) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of VLDLlevels (mg/dL) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of VLDL(Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 12 and day 45 in both interventional groups [Paired t-test].

Table 12-22 Change in baseline value of Triglycerides

Triglycerides (mg/dL)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	143.5±11.08	147.0±12.96	137.9±4.47	ns (0.7112)	ns (0.4415)
Vedicinals9 + Standard (SV9)	147.2± 10.16	143.0±7.25	151.8±4.75	ns (0.2714)	ns (0.9588)

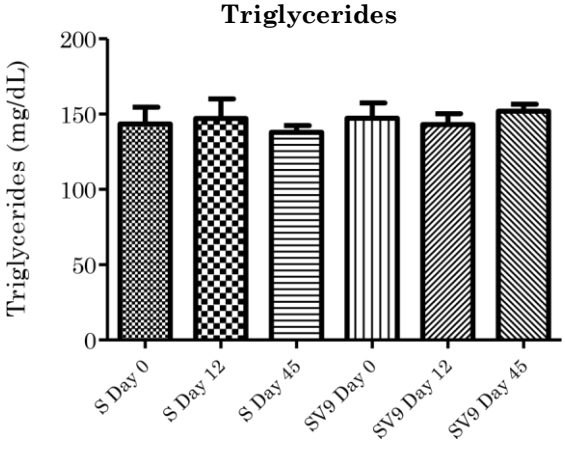

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Fig 12-22 Change in triglyceridelevels (mg/dL) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of triglyceridelevels (mg/dL) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of triglycerides(Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 12 and day 45 in both interventional groups [Paired t-test].

12.4.2.4 Other Biochemical estimations - FBS

Table 12-23 Change in baseline value of Fasting Blood Glucose (FBS)

FBS (mg/dL)					
Intervention	**Mean ± SEM**			***p*- value**	
	Day 0	**Day 12**	**Day 45**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	110.0±6.79	100.1±4.21	94.45±1.41	ns (0.0755)	*P (0.0258)
Vedicinals9 + Standard (SV9)	108.3±5.16	106.6±4.89	91.16±1.77	ns (0.5913)	***P (0.0008)

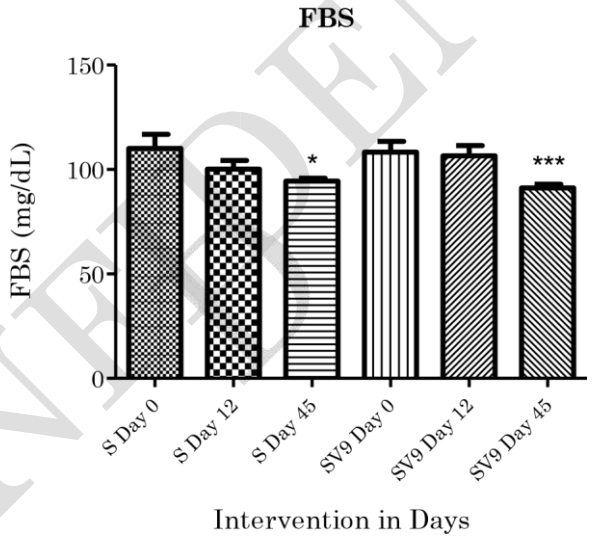

Fig 12-23 Change in FBS levels (mg/dL) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of FBSlevels (mg/dL) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of FBS (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 12 and day 45 in both interventional groups [Paired t-test].

12.5Vital signs, physical findings and other observations related to safety

12.5.1 Vital signs

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Vitals and demographic characteristics are presented in table below and indicate that the study population are homogeneous, with no statistically significant differences between the groups on baseline vitals and demographics.

The vital signs at all visits are provided in Appendix 16.4.

Table 12-24Summary of vitals at baseline compared between the groups.

Vitals	Mean ± SD		*P* - value
	Standard (S) (N=62)	Standard + Vedicials9 (SV9) (N=62)	Baseline S vs Baseline SV9
Height[a] (cms)	166.5 ± 1.26	166.0 ± 0.88	ns (0.7584)
Weight[a] (kg)	74.93 ± 1.89	73.25 ± 1.47	ns (0.4849)
Temperature[a] (F)	99.49 ± 0.22	99.48 ± 0.19	ns (0.9829)
Pulse Rate[a] (beats/min)	83.52 ± 0.86	82.61 ± 0.89	ns (0.4681)
Respiratory Rate[a] (breaths/min)	19.44 ± 0.26	19.05 ± 1.89	ns (0.2804)
SpO2[a] (%)	94.62 ± 0.45	95.39 ± 0.39	ns (0.2014)
BP[b]			
Baseline Systolic	125.3 ± 0.90	126.0 ± 0.96	ns
Baseline Diastolic	81.92 ± 0.92	80.65 ± 0.87	ns

[a]Analyzed by Unpaired t-test; [b]Analyzed by two-way ANOVA.

Table 12-25Summary of demographics at baseline compared between the groups.

Demographics	Mean ± SD		*P* - value
	Standard (S) (N=62)	Standard + Vedicials9 (SV9) (N=62)	S vs SV9
Age[a] (years) Mean ± SEM Median (Min-Max)	 40.71 ± 1.55 40.50 (18-60)	 38.82 ± 1.35 39.00 (18-60)	ns (0.3617)
Gender[b][n (%)] Male Female	 35 (56.45%) 27 (43.55%)	 33 (53.22%) 29 (46.78%)	ns (0.8569)
Nationality[b] [n (%)] Indian Other	 62 (100%) 0 (0.0%)	 62 (100%) 0 (0.0%)	ns (>0.99)
Marital status[b][n (%)] Married	 52 (83.87%)	 52 (83.87%)	ns (1.0000)

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Unmarried	10 (16.13%)	10 (16.13%)	
Study sites[b][n (%)] Delhi Bhopal	 28 (45.16%) 34 (54.84%)	 42 (67.74%) 20 (32.26%)	*P (0.0182)

[a] Analyzed by Unpaired t-test; [b] Analyzed by Fisher's exact test.

12.5.2 Physical Findings

The physical examinations at all visits are provided in Appendix 16.4.

Table 12-26Summary of Physical Examination at baseline compared between the groups.

Vitals	**Mean ± SD**		***P* - value**
	Standard (S) (N=62)	**Standard + Vedicials9 (SV9) (N=62)**	**Baseline S vs Baseline SV9**
General Appearance [n (%)] Normal Abnormal	 60 (96.78%) 2 (3.22%)	 62 (100%) 0 (0)	ns (0.4959)
Skin [n (%)] Normal Abnormal	 62 (100%) 0 (0)	 62 (100%) 0 (0)	ns (>0.99)
Eyes, Ears, Nose & Throat [n (%)] Normal Abnormal	 59 (95.16%) 3 (4.84%)	 57 (91.93%) 5 (8.07%)	ns (0.7173)
Head, Neck & Thyroid [n (%)] Normal Abnormal	 60 (96.78%) 2 (3.22%)	 62 (100%) 0 (0)	ns (0.4959)
Cardiovascular [n (%)] Normal Abnormal	 62 (100%) 0 (0)	 62 (100%) 0 (0)	ns (>0.99)
Respiratory [n (%)] Normal Abnormal	 40 (64.51%) 22 (35.49%)	 6 (9.68%) 56 (90.32%)	****P (<0.0001)
Abdomen [n (%)] Normal Abnormal	 62 (100%) 0 (0)	 62 (100%) 0 (0)	ns (>0.99)
Extremities [n (%)] Normal Abnormal	 62 (100%) 0 (0)	 62 (100%) 0 (0)	ns (>0.99)
Genitalia [n (%)] Normal Abnormal	 62 (100%) 0 (0)	 62 (100%) 0 (0)	ns (>0.99)

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Anorectal [n (%)] Normal Abnormal	 62 (100%) 0 (0)	 62 (100%) 0 (0)	 ns (>0.99)
Lymph Nodes [n (%)] Normal Abnormal	 62 (100%) 0 (0)	 62 (100%) 0 (0)	 ns (>0.99)
Muscular-Skeletal [n (%)] Normal Abnormal	 62 (100%) 0 (0)	 62 (100%) 0 (0)	 ns (>0.99)
Neurological [n (%)] Normal Abnormal	 62 (100%) 0 (0)	 62 (100%) 0 (0)	 ns (>0.99)

12.5.3 X-Ray

The X-ray findings of individual patient is provided in Appendix 16.4.

Table 12-27Summary of X-Ray in both the groups.

X-Ray	Standard (S)			Standard + Vedicinals9 (SV9)		
	S Day 0 (N=62)	S Day 12 (N=62)	S Day 45 (N=60)	SV9 Day 0 (N=62)	SV9 Day 12 (N=61)	SV9 Day 45 (N=59)
Normal [n (%)]	39 (62.90%)	39 (62.90%)	57 (95.00%)	6 (9.68%)	47 (77.05%)	57 (96.61%)
Abnormal [n (%)]	23 (37.10%)	23 (37.10%)	3 (5.00%)	56 (90.32%)	14 (22.95%)	2 (3.39%)

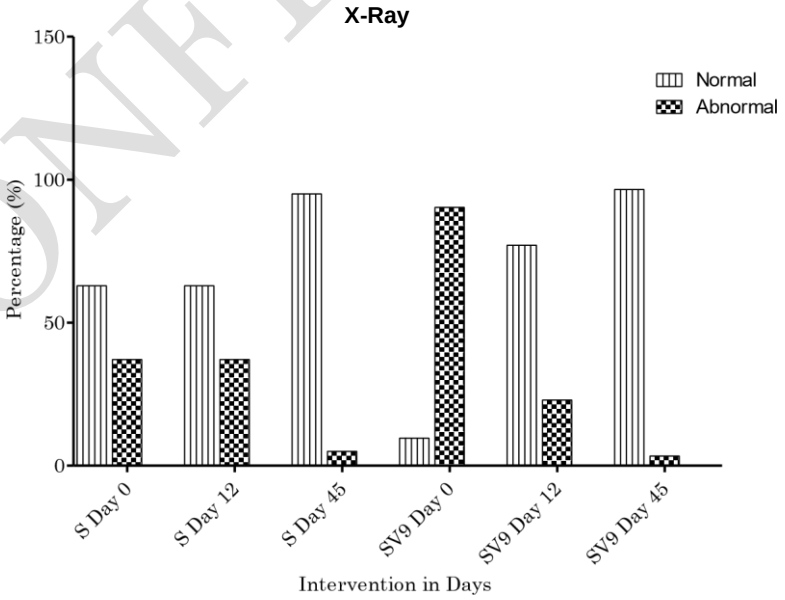

Fig 12-24X-Ray findings of COVID-19 positive patients from day 0 to 45. Data interpret following: Percentage of COVID-19 positive patients from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as

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percentage of patients with normal and abnormal findings of X-ray in two comparable interventional group (n=62 per group).

Before the start of the treatment at day 0, 37.10% (23/62) of cases had abnormal x-ray findings in standard group and 90.32% (56/62) in vedicinals-9 adjuvant group. After 12 ± 2 days of treatment, only 22.95% (14/61) of cases had abnormal findings in vedicinals-9 adjuvant group resulting in 77.05% (47/61) of cases with normal findings compared to standard group alone which showed no change at all from day 0.

12.5.4 PT and INR

Table 12-28Change in baseline value of Prothrombin Time (PT)

PT (sec)							
Intervention	**Mean ± SEM**				***p*- value**		
	Day 0	**Day 5**	**Day 12**	**Day 45**	**Day 0 Vs 5**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	16.61±0.24	16.56± 0.26	16.48± 0.25	16.64± 0.34	ns (0.7638)	ns (0.4095)	ns (0.7747)
Vedicinals9 + Standard (SV9)	16.15±0.27	15.95±0.48	15.70± 0.35	15.66± 0.31	ns (0.6262)	ns (0.1388)	ns (0.1022)

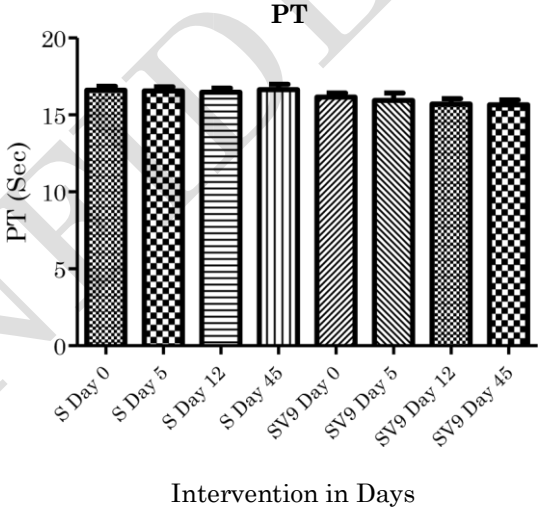

Fig 12-25 Change in PT levels (mg/dL) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of PT levels (mg/dL) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of PT (Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 5, 12 and day 45 in both interventional groups [Paired t-test].

Table 12-29Change in baseline value of International Normalized Ration (INR)

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INR							
Intervention	**Mean ± SEM**				***p*- value**		
	Day 0	**Day 5**	**Day 12**	**Day 45**	**Day 0 Vs 5**	**Day 0 Vs 12**	**Day 0 Vs 45**
Standard (S)	1.19± 0.19	1.20± 0.21	1.20± 0.02	1.19± 0.02	ns (0.6528)	ns (0.6553)	ns (0.9230)
Vedicinals9 + Standard (SV9)	1.15± 0.02	1.12± 0.01	1.16± 0.02	1.12± 0.02	*P (0.0314)	ns (0.8959)	ns (0.2384)

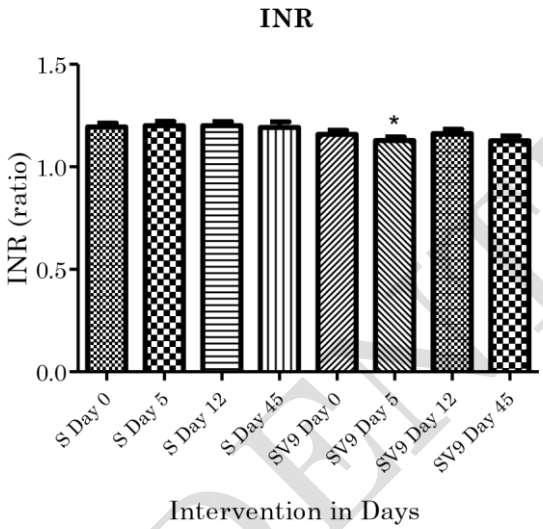

Fig 12-26 Change in INR levels (mg/dL) of COVID-19 positive patients from day 0 to 45. Data interpret following: Change of INRlevels (mg/dL) from day 0 to day 45, when vedicinals9 5000mg adjuvant with standard intervention compared with standard intervention alone. Data represented as change in baseline values of INR(Mean ± SEM) in two comparable interventional group (n=62 per group). Significant at *p<0.05, **p<0.01, ***p<0.001, ****P<0.0001, when compared before and after intervention at day 5, 12 and day 45 in both interventional groups [Paired t-test].

12.5.5 Special safety topics

None.

12.6 SUMMARY OF SAFETY RESULTS

There were no deaths or SAEs reported during the study.

One non-serious AE (Headache) was reported by the one patient who was randomized to standard. The AE of headache was mild in severity and was not related to the study medication. There were no AEs leading to discontinuation reported during the study.

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The vital signs measurements and symptoms scores at each study visit for the patients who was randomized to both the treatments can be found in Table 12-1 and Table 12-2 respectively.

13 DISCUSSION AND OVERALL CONCLUSIONS

This was a phase II-b study with the objective to determine the incremental lowering of disease progression in mild to moderate COVID-19 cases that is achieved when Vedicinal-9 is used adjunctively to standard treatment for clinical management in patients with altered pathophysiology and disease progression.The lack of standard treatment for COVID-19 creates the need for investigation of strategies that can either target SARS-CoV-2 to eliminate it or to improve the symptomatology and strengthen the natural defences. We aimed on both the option and evaluated the use of an add-on therapy by enrolling a total of 124 COVID-19 patients, male 54.8% (68/124); mean age of 39.37 years, female 45.2 (56/124) mean age of 38.04 years randomized into standard and vedicinals-9 adjuvant group for 14 days' interventional period followed by 30 days of follow up (45 days).Comparing the two treatment, a clear difference was seen in the resolution of most symptoms, including fever, dry cough, fatigue, myalgia, sore throat, hypoxia, dyspnea and weakness. Overall, the reduction in time for the resolution of the symptoms indicate a possible positive effect for Vedicinals-9 as an add-on therapy for COVID-19. Robust studies showing the time for recovery of symptoms are still lacking, as most of them focus on the time for symptom onset and in the rate of recovery/complications. The time from exposure to symptom onset is usually reported as is in average 11.5 days, and the time between symptom onset and hospital admission about 7 days. Usually the first symptoms (Stage I: fever, dry cough, headache, diarrhoea) appear between 0 to 4 days; the Stage II symptoms (hypoxia) in 5-13 days; and Stage III symptoms (ARDS, cardiac failure, shock) after 14 days of infection. This is in concordance with what was found by *Wang et al*, a median 5 days (range 2-8 days) for the progression from mild-moderate cases to severe condition, and a hospital stay range from 14 to 22 days.

One of the studies by *Carfi et al*. assessed patients for a mean of 60.3 days after onset of the first COVID-19 symptom and observed that only 12.6% were completely free of any COVID-19–related symptom, while 32% had 1 or 2 symptoms and 55% had 3 or more. A report from Imperial College of London showed that the mean time for recovery after symptom onset is 20.51 (± 6.69) days.In contrast, 59.68% of the Vedicinals-9 adjutant treatment of the present study recovered during the first observational period (5±2 days) followed by remaining 40.32 in the next observation period of 14±2 days compared to the standard treatment alone 37.10% followed by 62.90% in 5±2 days and 14±2 days respectively, and the most common symptoms were resolved within around 2 to 5 days A similar population studied was also reported by *Chen et al.*[26]: patients with mild cases, a median of 51 years, and a percentage of 50.6% men. In this study, the estimated median duration of fever was 10 days (CI: 8-11 days), after onset of

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symptoms – in our findings, The Vedicinals-9 adjuvant group had a mean duration of fever of 3.5 days compared to 4.12 days for prolonged fever cases, while fever recurred at a mean of 11.53 days compared to 11.83 days for those with saddleback fever cases. Obtaining fast patient recovery is important, as the persistence of symptoms can reflect the worsening in his prognosis. For example, for severe cases, the symptoms can last for more than 28 days, leading to hyperinflammation/hypercoagulation responses and pulmonary fibrosis formation. The improvement in the time needed for recovery of the symptoms in the Vedicinals-9 treatment can be related to the multiple mechanisms that the components of the Vedicinals-9 theoretically act on as described earlier by the inventor *Joachim et al*.We will highlight four. First, immune system regulation. This can be related to macrophage activation with CCL2 regulation by Baicalin, Quercetin, Luteolin, Curcuminoids, Polyphenols and Glycyerrhizin, to activation of NK-cells by Baicalin, Quercetin, Luteolin and Curcuminoids, to the increase in T-cells functions by all 9 phyto molecules of vadicinals-9 (Baicalin, Quercetin, Luteolin, Rutin, Hesperidin, Curcuminoids, Polyphenols, Piperine and Glycyerrhizin), and to CD4+ cells activation, which can regulate the antigenic stimulus triggering CD4+ Th1 cells to produce IFN-, IL-1 and TNF-α. In addition, Vedicinals-9 positively regulates Th1 cytokines, while decreases the release of Th2 cytokines (IL-4, IL-5, IL-6, IL-13). This is relevant once there is evidence that the Th2 overresponse are linked to bronchoconstriction, dyspnea and exacerbations of allergic airways diseases.

Secondly, targeting the virus itself by: (i) avoiding the virus to enter the cell: Quercetin, Rutin, Curcuminoids andPolyphenols have shown DPP4R inhibitory effect, and Baicalin, Quercetin, Rutin, Hesperidin, Curcuminoids, Polyphenolsshowed potential to block the binding of RBD-ACE2 6VW1 at the molecular level; all 9 phyto molecules of vadicinals-9 (Baicalin, Quercetin, Luteolin, Rutin, Hesperidin, Curcuminoids, Polyphenols, Piperine and Glycyerrhizin) have shown 3C-Like protease 6LU7 inhibitory effect and Hesperidin showed potential inhibitory activity for spike, envelop and nucleocapsid protein; and (ii) decreasing virus replication: Quercetin, Rutin, Piperine and Glycyerrhizin inhibits the replication of SARS coronavirus (SARSCoV) and other RNA viruses, through inhibition of RNA polymerase. Also, Ingredients inhibits virus replication by down regulating relevant enzymes like Furin, Trypsin and GRP 78. Vedicinals-9 can act synergistically with Zinc, as it has been shown to increase the intracellular entrance of Zinc via acting as Zinc ionophores (Baicalin, Polyphenol, Glycyerrhizin). In addition, Vedicinals-9 might be expected to help to prevent and control RNA virus infections because they up and down regulate various host receptors, cells and enzymes along with structural alteration in proteins of SARS-CoV-2.

Third, the Vedicinals-9 effects the inflammatory process generated by the infection. As all 9 phyto molecules of Vedicinals-9 exhibits anti-inflammatory properties, it could potentiate innate immunity while controlling the potentially harmful inflammatory response. This immunoregulatory effect could in turn

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prevent hyperinflammatory response caused by respiratory tract infections. In fact, Vedicinals-9 can decrease the IL-6 effect and C-Reactive Protein, which are known marker of poor outcome in critically ill patients. For example, the evaluation of a large number of patients in this study has demonstrated thatVedicinals- may reduce COVID-19 severity by a suppressive effect on the cytokines storm, and therefore improve clinical outcomes of patients. Vedicinals9, can increase lymphocyte B and T proliferation and differentiation at a controlled rate. Vedicinals-9 can inhibit the signalling pathway, which provides potential protection against tissue damage (including lung) coming from excessive inflammatory response. Among the potential pharmacological effects of Vedicinals-9 figures the decrease of the serological concentration of TNF-α and IL-6, the suppression in TLR4 expression and the reduced activation of MAPK and NF-κB. All ingredient, were shown recently to decrease inflammation through inhibition of the release of cytokines (IL-6and TNF-α) and chemokines (CCL2).

Finally, the add-on treatment provided was idealized to also act on the oxidative stress. Vedicinlas-9 induces various peroxidase enzymes (enzymes that neutralize hydrogen peroxidase, a reactive oxygen species) and promote synthesis of glutathione. Besides, other ingredients with antioxidant properties such as Luteolin, Rutin, Hesperidin, Curcuminoids, Polyphenols (Epigallo catechin gallate) and Piperine also contribute to reduce the oxidative stress. Others tissue regenerative, myocardial, anti-thrombotic and long COVID-19 protection is also being potentially noticed.

Conclusion

This retrospective study demonstrates a potential promising role of Vedicinals-9 as adjuvant therapy on the evolution of symptomatology, strengthen the natural defences to COVID-19 patients and in post COVID-19 secondary complication. Specially for the symptoms fever, dry cough, dyspnoea, headache, diarrhoea and weakness, reduction of viral load and the recovery time for the treated patients was significant shorter in comparison to the standard treatment. In addition, post COVID-19 secondary complication like Cardiovascular, Neurological, Pulmonary, Renal, Myocardial, Hepatic and Pancreatic were attenuated in the adjuvant treated patients in comparison to the standard treatment alone.

14. TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

Refer page no. 13-14 of the report.

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15. REFERENCE LIST

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16 APPENDICES

16.1 STUDY INFORMATION

Appendix 16.1.1: Protocol and Protocol Amendment

Protocol V1_17.09.2020	EPDR0202-010920_V edicinals_COVID-19_P
Protocol V1R1_28.09.2020 (Site1-Delhi)	EPDR0202-010920_V edicinals_COVID-19_P

Protocol V1R1_28.09.2020 (Site2-Bhopal site)	EPDR0202-010920_V edicinals_COVID-19_P

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16.1.2 Sample case report form (unique pages only)

Sample case report form	EPRD0202-010920_ Covid_CRF_Final_V1.
Visit 1	1. CRF_Screening.pdf
Visit 2	2. CRF_Randomization [
Visit 3	3. CRF_Day 5.pdf
Visit 4	4. CRF_Day 12.pdf
Visit 5	5. CRF_Day 45.pdf
AE/SAE Forms, Concomitant medication log, Unscheduled tests/events log	6. CRF_Forms, logs and completion.pdf

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16.1.3 List of IECs, Approvals and Sample Consent Forms

A. List of Institutional and Independent Ethics Committee

1.	Institutional Ethics Committee, Aakash Healthcare Super Speciality Hospital, New Delhi, India	Dr. Arun K Agarwal, Chair Person Dr. Meinal Chaudhary Member Secretary
2.	Vision Independent Ethics Committee, Parth Solitaire, Office No. 209, 2nd Floor, Plot no.2, Sec 9E, Kalamboli, Navi Mumbai – 410218, Maharashtra, India	Dr. Sainath Doiphode Chair Person Dr. Bharat Namvar Member Secretary

B. List of Institutional and Independent Ethics Committee Approvals

1.	Institutional Ethics Committee, Aakash Healthcare Super Speciality Hospital, New Delhi, India	EPRD0202-010920_EC Approval letter Aak
2.	Vision Independent Ethics Committee, Parth Solitaire, Office No. 209, 2nd Floor, Plot no.2, Sec 9E, Kalamboli, Navi Mumbai – 410218, Maharashtra, India	EPRD0202-010920_EC Approval letter Chir

C. Sample Consent Forms

ICF Master	EPRD0202-010920_Vedicinicals_Covid-19_
ICF (Site 1 – Delhi)	EPRD0202-010920_Vedicinicals_Covid-19_
ICF (Site 2 – Bhopal)	EPRD0202-010920_Vedicinicals_Covid-19_

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16.1.4 List and description of investigators and other study personnel's

A. List of Investigator and Study Personnel's at Aakash Healthcare, Delhi, India

S. No.	Study Personnel's Site 1 – Delhi	Name
1	Principal Investigator	Dr. Navneet Singh Gill
2	Co-Investigator (1)	Dr. Ankit Agarwal
3	Co-Investigator (2)	Dr. Akshay Budhraja
4	Co-Investigator (3)	Dr. Deepesh Megwani
5	Study Coordinator	Mrs. Neetu Nanda
6	Clinical Research Coordinator (1)	Mr. Aakarsh Tyagi
7	Clinical Research Coordinator (2)	Ms. Jyoti Rathore
8	Clinical Research Coordinator (3)	Ms. Sapna Singh
9	Clinical Research Coordinator (4)	Ms. Preeti
10	Laboratory investigator	Dr. Harpreet Kaur

B. List of Investigator and Study Personnel's at Chirayu Medical College and Hospital, Bhopal, India

S. No.	Study Personnel's Site 2 – Bhopal	Name
1	Principal Investigator	Dr. Rohit Parate
3	Co-Investigator (1)	Dr. Krishna Gopal Singh
4	Study Coordinator	Mr. Mukul Maurya
5	Clinical Research Coordinator (1)	Mr. Akram Khan
6	Clinical Research Coordinator (2)	Ms. Nitisha Bramhe
7	Laboratory investigator	Dr. Samir Singh

C. List of Monitors and Study Personnel's at CRO

S. No.	Study Personnel's CRO	Name
1	Contact Person (Public & Scientic Query)	Mr. Yogendra Kumar Choudhary
3	Project Manager and QA	Ms. Yesha Ramani

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4	Asst. Project Manager	Ms. Babita Pandey
5	Clicinal Trial Asistant (CTA)	Ms. Mahak Beg
6	Biostatistician	Consultant

16.1.5 Signatures of principal or coordinating investigator(s) or

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sponsor's responsible medical officer

PRINCIPAL OR COORDINATING INVESTIGATOR(S) SIGNATURE(S) OR SPONSOR'S RESPONSIBLE MEDICAL OFFICER

STUDY TITLE: A randomized, open label, parallel efficacy, active control, multi-centre exploratory trial to evaluate efficacy and safety of vedicinals-9, an herbal formulation as adjunct treatment to standard of care for the management of mild to moderate covid-19 patients.

STUDY AUTHOR(S):**1. Mr. Joachim Gerlach,**
2. Mr. Prakash Pundlik Salunke,
3. Mr. Yogendra Kumar Choudhary

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study

INVESTIGATOR(S) OR SPONSOR'S RESPONSIBLE MEDICAL OFFICER:

1. DR. NAVNEET SINGH GILL SIGNATURE(S)

2. DR. ROHIT PARATE

AFFILIATION: *1. Dr. Navneet Singh Gill, Consultant (MBBS, DNB-Family Medicine), Aakash Healthcare Super Speciality Hospital, New Delhi, India*

2. Dr. Rohit Parate, Consultant General Medicine (MBBS, MD-Medicine), Chirayu Medical College and Hospital, Bhopal, Madhya Pradesh, India

DATE:

16.1.6 Listing of standard medicinal product(s)

A. List of standard medication at Aakash Healthcare, Delhi, India

S. No.	Therapeutic Category	Active	Frequency
1	Antipyretic	Paracetamol (500 mg)	
2	Supplement(s) and multivitamin(s)	Calcium, Methyl Folate + Methycobalamine + Pyridoxine, Vitamin C /Ascorbic acid (1.5mg; 500mg), Vitamin D3/ Cholecalciferol (60000 IU), Protein Powder, [Ginseng 42.5 mg +Astaxanthin 1 mg +Vitamin A 2500 IU +Ascorbic Acid (Vit C) 25 mg + Tocopherols (Vit E) 9], [Vitamin C / Ascorbic Acid + Sodium Ascorbate + Zinc Oxide + Vitamin D3 / Cholecalciferol +Vitamin A / Retinol], [Copper(30.0 Mcg) + Iodine(100.0 Mcg) + Vitamin A / Retinol(600.0 Mcg) + Vitamin C / Ascorbic Acid(40.0 Mg) + Grape Seed Extract(50.0 Mg) + Vitamin B7 / Biotin / Vitamin H(150.0 Mcg) + Vitamin B3 / Nicotinic Acid / Niacin(18.0 Mg) + Vitamin B6 / Pyridoxine(1.0 Mg) + Vitamin E / Tocopherol(10.0 Mg) + Vitamin B9 / Folic Acid / Folate(100.0 Mcg) + Chromium(25.0 Mcg) + Zinc(10.0 Mg) + Vitamin B1 / Thiamine(1.4 Mg) + Selenium(30.0 Mcg) + Magnesium(3.0 Mg) + Vitamin B12 / Mecobalamin / Cynocobalamin / Methylcobalamin(1.0 Mcg) + Manganese (250.0 Mcg) + Vitamin B2 / Riboflavin (1.6 Mg) + Vitamin D3 / Cholecalciferol (5.0 Mcg) + Vitamin B5 / Pantothenic Acid (3.0 Mg)], Vitamin B Complex	
3	Zinc	Zinc Acetate (50 mg)	
4	Antibiotic(s)	Azithromycin (500mg), Clobarium (5mg), Doxycycline (100mg), Cefepime (1000 mg), Ceftriaxone (1gm), Piperacillin (4000mg) + Tazobactum (500mg), Cefuroxime (500mg), Doxycycline (100mg) + Lactobacillus	
5	Antimalarial(s) & Antiparasitic(s):	Clobarium (5mg), Doxycycline (100mg), Cefepime (1000 mg), Ceftriaxone (1gm), Piperacillin (4000mg) + Tazobactum (500mg), Cefuroxime (500mg), Doxycycline (100mg) + Lactobacillus	
6	Corticosteroid(s):	Methylprednisolone (4 mg), Dexamethasone (4 mg)	
7	Low mol. wt. heparin(s):	Enoxaparin (40 mg)	
8	Anti-Viral(s):	Remdesivir (40 mg), Favipiravir(200mg)	
		Acebrophylline (100 mg) + Acetylcysteine (600 mg), [Phenylephrine (5 mg/5 ml) + Chlorpheniramine Maleate (2 mg/5 ml) + Dextromethorphan Hydrobromide (15 mg/5	

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9	Mucolytic(s):	ml)], [Phenylephrine (5mg/5ml) + Chlorpheniramine Maleate (2mg/5ml) + Dextromethorphan Hydrobromide (10mg/5ml)], [Guaifenesin (50mg) + Terbutaline (1.25mg) + Bromhexine (2mg)], [Codeine (10mg/5ml) + Triprolidine (1.25mg/5ml)], [Aluminium Hydroxide 250mg + Magnesium Hydroxide 250mg + Dimethicone 50mg], [Ammonium Chloride (60mg/5ml) + Chlorpheniramine Maleate (2.5mg/5ml) + Dextromethorphan Hydrobromide (5mg/5ml) + Guaifenesin (50mg/5ml)], [Levocloperastine (20mg/5ml) + Chlorpheniramine Maleate (4mg/5ml)], [Levocloperastine (20mg/5ml) + Chlorpheniramine Maleate (4mg/5ml)],	
10	Anti-hypertensive and blood pressure(s):	Amlodipine (5.0 mg), Telmisartan (40mg) + Metoprolol Succinate (25mg), Levocarnitine500mg + Ubiquinone-30mg	
11	Anti-vomiting and antiulcer(s):	Domperidone (30mg) + Rabeprazole (20 mg), Pantoprazole (40mg), Ondansetron (4 mg), Domperidone (30mg) + Pantoprazole (40mg), Esomeprazole (40mg), Sucralfate (500mg/5ml)	
12	Anti-hyperglycemic(s):	Teneligliptin (20 mg), Metformin (1000mg) + Vildagliptin (50mg)	
13	Anti-hypothyroid(s):	Thyroxine (100 mcg)	
14	Insulin(s)	Insulin Glargine (100 IU)	
15	Diuretic(s):	Furosemide (10mg/ml)	
16	Anti-allergic(s):	Levocetirizine (5mg) + Montelukast (10mg), Randitidine (150 mg), Desloratadine (5mg) + Montelukast (10mg), Montelukast (10mg),	
17	Anti-Idiopathic pulmonary fibrosis (IPF) agent(s)	Pirfenidone (200mg)	

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B. List of standard medication at Chirayu Medical College and Hospital, Bhopal, India

S. No.	Therapeutic Category	Active	Frequency
1	Antipyretic	Paracetamol (500 mg)	
2	Supplement(s) and multi-vitamin(s)	Calcium and Vitamin D3 (500 mg), [Vitamin A IP (as acetate):10,000 IU, Vitamin B1 (Thiamine Mononitrate IP): 10 mg, Vitamin B2 (Riboflavin IP): 10 mg,, Vitamin B3 (Nicotinamide IP): 100 mg, Vitamin B5 (Calcium Pantothenate IP): 16.30 mg, Vitamin B6 (Pyridoxine Hydrochloride IP): 3 mg, Vitamin B 7 (Biotin USP): 0.25 mg, Vitamin B12 (Cyanocobalamin IP): 15 mcg, Vitamin C (Ascorbic Acid IP): 150 mg, Vitamin D3 (Cholecalciferol IP): 1,000 IU, Vitamin E (α-Tocopheryl Acetate IP): 25 mg, Calcium (Tribasic Calcium Phosphate IP): 129 mg, Magnesium (Magnesium Oxide Light IP): 60 mg, Iron (Dried Ferrous Sulphate IP): 32.04 mg, Manganese (Manganese Sulphate Monohydrate BP): 2.03 mg, Phosphorus (Total Phosphorus): 25.80 mg, Copper (Copper Sulphate Pentahydrate BP): 3.39 mg, Zinc (Zinc Sulphate IP): 2.20 mg, Molybdenum (Sodium Molybdate Dihydrate BP): 0.25 mg, Boron (Sodium Borate BP): 0.88 mg, [Vitamin C /Ascorbic acid (500 mg)]	
3	Zinc	Zinc Acetate (50 mg)	
4	Antibiotic(s)	Azithromycin (500mg)	
5	Corticosteroid(s):	Dexamethasone (4 mg)	

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16.1.7 Randomisation scheme and codes

Randomization Scheme and codes	EPRD0202-010920_ Master Randomization
Randomization codes (Site 1 – Delhi)	EPRD0202-010920_ COVID-19 HCT_Rando
Randomization codes (Site 2 – Bhopal)	EPRD0202-010920_ COVID-19 HCT_Rando

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16.1.8 Monitoring Report &QA certificates

Monitoring Report_V1_ (Site1-Delhi)	
Monitoring Report_V1_ (Site2-Bhopal site)	

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QUALITY ASSURANCE CERTIFICATE
MONITOR(S) SIGNATURE(S)

STUDY TITLE:

A randomized, open label, parallel efficacy, active control, multi-centre exploratory trial to evaluate efficacy and safety of vedicinals-9, an herbal formulation as adjunct treatment to standard of care for the management of mild to moderate covid-19 patients.

STUDY MONITOR(S): **1. Mr. Yogendra Kumar Choudhary**
2. Ms. Yesha Ramani

STATEMENT

This trial was conducted in accordance with the ethical principles of Declaration of Helsinki (ICH –GCP), approved protocol by Ethics Committee (EC) and in compliance with ICMR Ethical Guidelines 2017. The clinical trial information was recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification according to the ICH-GCP E6 (R2) Nov 2016. Every individual involved in conducting this trial was qualified by education, training, and experience to perform his / her respective responsibility as per GCP.

The quality assurance and quality control systems implemented to assure the quality of the data was as per internal SOP of site, laboratory and monitoring CRO. Consistence external monitoring, training and data audits was done to ensure the use of standard terminology, collection of accurate, consistent, complete, and reliable data.

I confirm that this study was conducted according to compliances to the best of my knowledge and accurately describes the ethical conduct and my signature below constitutes my acknowledgment of undertaking third party Quality assurance.

MONITORS(S)

1. **YOGENDRA KUMAR CHOUDHARY** SIGNATURE(S) 

2. **YESHA RAMANI**

AFFILIATION: Ethix Pharma, 315-317, Ambuja City Centre, Vidhan Sabha Road, Mowa, Raipur – 492001, C.G, INDIA

DATE:

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16.1.9 CTRI Registration Number & Document

CTRI Registration	EPRD0202-010920_ Covid-19 study_CTRI

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16.1.10 Documentation of laboratory accreditation & certification

Lab Accreditation (Site1-Delhi)	NABL accreditation.pdf Extension_in_Validity _of_Accreditation.pdf
Lab Accreditation (Site2-Bhopal site)	Lab Accreditation Certificate MC-4161.p

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16.1.11 Certificate of Analysis – Investigation Product (3 Batches)

COA_Batch No._S/SCL/20001	COA_Batch S-SCL-20001.pdf
COA_Batch No._S/SCL/20002	COA_Batch S-SCL-20002.pdf
COA_Batch No._S/SCL/20003	COA_Batch S-SCL-20003.pdf

16.1.12 Important publications based on study & referenced in the report

To be included.

16.2. PATIENT DATA LISTINGS

16.2.1 Discontinued patients

STUDY # Vedicinals-9 Adjuvant HCT

(Data Set Identification)

LISTING OF PATIENTS WHO DISCONTINUED THERAPY

Centre:Aakash Healthcare, Delhi, India

Treatment	Patient #	Sex	Age	Last Visit	Duration	Dose	Concomitant Medication	Reason for Discontinue
Standard	0166	F	33	Day 12±2	13 days	Taxim O (BD), Scavista (OD), Dolo (SOS), Teczine-M (OD), Syp Alex, Somprez (OD), Becosule-Z (OD), Limcee (BD)	None	Lost to follow-up

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Treatment	Patient #	Sex	Age	Last Visit	Duration	Dose		Concomitant Medication	Reason for Discontinue
Standard	0167	M	30	Day 12±2	13 days		Azee (OD), Dolo (SOS), Montair LC (OD), Pantocid DSR (OD), Ivermet (OD), BecosuleZ (OD), Limcee (BD)	None	Lost to follow-up

Treatment	Patient #	Sex	Age	Last Visit	Duration	Dose		Concomitant Medication	Reason for Discontinue
Standard + Vedicinals9	0102	F	38	Day 5 ± 2	4 days	5000mg per day of 50ml of	and Standard care - Medral (OD), Syp. Corex T (OD), Bandy Plus, Pirfenex (TDS), Lumia (OD), Protein Powder (BD)	None	Withdrawn by patient Vedicinals-9

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Treatment	Patient #	Sex	Age	Last Visit	Duration	Dose	Concomitant Medication	Reason for Discontinue
Standard + Vedicinals9	0169	F	31	Day 12±2	14 days	5000mg per day of 50ml of Vedicinals-9 and Standard care - Azee (OD), Dolo (SOS), Teczine-M (OD), Syp Alex (TDS), Becosule-Z (OD), Limcee (BD), Sompraz (OD)	None	Lost to follow-up

Treatment	Patient #	Sex	Age	Last Visit	Duration	Dose	Concomitant Medication	Reason for Discontinue
Standard + Vedicinals9	0170	M	28	Day 12±2	14 days	5000mg per day of 50ml of Vedicinals-9 and Standard care - Azee (OD), Dolo (OD), Teczine (OD), Scavista (OD), ZU-C (BD), Becosule (OD)	None	Lost to follow-up

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STUDY # Vedicinals-9 Adjuvant HCT

(Data Set Identification)

LISTING OF PATIENTS WHO DISCONTINUED THERAPY

Centre:Chirayu Medical College and Hospital, Bhopal, India

Treatment	Patient #	Sex	Age	Last Visit	Duration	Dose	Concomitant Medication	Reason for Discontinue
Standard	NA	NA	NA	NA	NA	NA	NA	NA

Treatment	Patient #	Sex	Age	Last Visit	Duration	Dose	Concomitant Medication	Reason for Discontinue
Standard + Vedicinals-9	NA	NA	NA	NA	NA	NA	NA	NA

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16.2.2 Protocol deviations

Subject no.	Protocol deviation at	Expected date	Actual date	Visit on
0105	Day 12±2 days	30-Dec-2020	3-Jan-2021	16th day
0103	Day 45±2 days	31-Jan-2021	4-Feb-2021	49th day

16.2.3 Patients excluded from the efficacy analysis

STUDY # Vedicinals-9 Adjuvant HCT

(Data Set Identification)

LISTING OF PATIENTS AND OBSERVATIONS EXCLUDED FROM EFFICACY ANANLYSIS

*Centre:*Aakash Healthcare, Delhi, India

Treatment	Patient #	Sex	Age	Observation Excluded	Reason(s)
Standard	0166	F	33	Day 45 ± 2 – All observations	Patient discontinued

Treatment	Patient #	Sex	Age	Observation Excluded	Reason(s)
Standard	0167	M	30	Day 45 ± 2 – All observations	Patient discontinued

Treatment	Patient #	Sex	Age	Observation Excluded	Reason(s)
Standard + Vedicinals9	0102	F	38	Day 12 ± 2 – All observations Day 45 ± 2 – All observations	Patient discontinued

Treatment	Patient #	Sex	Age	Observation Excluded	Reason(s)
Standard + Vedicinals9	0169	F	31	Day 45 ± 2 – All observations	Patient discontinued

Treatment	Patient #	Sex	Age	Observation Excluded	Reason(s)

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Standard + Vedicinals9	0170	M	28	Day 45 ± 2 – All observations	Patient discontinued

STUDY # Vedicinals-9 Adjuvant HCT

(Data Set Identification)

LISTING OF PATIENTS AND OBSERVATIONS EXCLUDED FROM EFFICACY ANANLYSIS

*Centre:*Chirayu Medical College and Hospital, Bhopal, India

Treatment	Patient #	Sex	Age	Observation Excluded	Reason(s)
Standard	NA	NA	NA	NA	NA

Treatment	Patient #	Sex	Age	Observation Excluded	Reason(s)
Standard + Vedicinals9	NA	NA	NA	NA	NA

16.2.4 Demographic data

See section 11.2

16.2.5 Compliance and/or drug concentration data (if available)

See section 11.3

16.2.6 Adverse event listings (each patient)

Not applicable. No AE reported.

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16.3 CASE REPORT FORMS

16.3.1 CRFs for deaths, other SAE and withdrawals for AE

Not applicable

16.3.2 Other CRFs submitted

See appendix 16.1.3

16.4. INDIVIDUAL PATIENT DATA LISTINGS

Individual Patient Data Listing Standard Group	Appendix 16.4a_Individual Patie
Individual Patient Data Listing Vedicinals-9 Group	Appendix 16.4b_Individual Patie

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