

Covid-19 Clinical Trails Conducted at

Dr. Vithalrao Vikhe Patil Foundations Medical College and Hospital, Maharashtra,India



Utility of Medihope as an addon therapy for Covid 19 patients: An Open labeled, Non-Randomized, Multicentric, Phase III Clinical.

Utility of Medihope as an addon therapy for Covid 19 patients: An Open labeled, Non-Randomized, Multicentric, Phase III Clinical.

Contents	Page No.
1. ABSTRACT	3
2. BACKGROUND	5
3. MATERIAL & METHODS	11
4. RESULTS	21
5. DISCUSSION	92
6. CONCLUSION	99
7. REFERENCES	100

INDEX

Name, address & contact details of the sponsor: "Hope" Ayurvedic Medicine Pvt. Ltd.

S. No.	Center	Investigators
1	Dedicated Covid Hospital,	1. Dr. Rahul Kunkulol, Professor & Head,
	Loni.	Pharmacology, RMC, Loni.
		2. Dr. Mahajan, Professor & Head, Medicine,
		RMC, Loni.
		3. Dr. Sandeep Narwane, Associate Professor,
		Pharmacology, RMC, Loni.
		4. Dr. Anup Kharde, Associate Professor,
		Community Medicine, RMC, Loni.
		5. Dr. Shekokar, Professor & Head, Shalya
		Tantra, SVNHT Ayurveda College, Rahuri.
		6. Mr. Kalpesh Game, CRC, Research Cell,
		PIMS (DU), Loni.
2	Swargiya Shrimati Sindhutai	
	Vikhe Patil, Covid Care	
	Center, Ahmednagar.	

Name and designation of the Investigators:

1. ABSTRACT

Title:	Utility of Medihope as an addon therapy for Covid 19 patients: An Open labeled, Non-Randomized, Multicentric, Phase III Clinical.				
Objectives:	 Primary objective: To compare the efficacy of Is Medihope with standard treatment VS Standard treatment alone with respect to changes in SpO2 levels and X ray c h e s t of COVID 19 positive patients admitted to Dedicated Covid Hospital, Loni and Swargiya Shrimati Sindhutai Vikhe Patil, Covid Care Center, Ahmednagar. Secondary objective: To compare the efficacy of Is Medihope with standard treatment VS to Standard treatment alone with respect to changes in temperature, respiratory symptoms and change in CBC & Duration of stay of COVID 19 positive patients admitted to Dedicated Covid Hospital, Loni and Swargiya Shrimati Sindhutai Vikhe Patil, Covid Care Center, Ahmednagar. 				
Outcome measures	Primary: SpO2 levels X ray c h e s t Secondary: Temperature, respiratory symptoms and change in CBC & Duration of stay				
Population:	Patients infected with Covid 19 detected by RTPCR (Real-Time Reverse Transcription Polymerase Chain), TrueNat or Corona Rapid Test admitted and receiving treatment in Dedicated Covid Hospital, Loni and Swargiya Shrimati Sindhutai Vikhe Patil, Covid Care Center, Ahmednagar.				
Phase:					
Study Design.	Open label Non-Randomized				
Study Duration:	1 vear				
Participant's	7 days				
participation	,				
Duration:					
Description of study	A. ICMR Standard treatment				
intervention:	B. ICMR Standard treatment + Medihope supplementation				

Results	The groups were comparable with respect to gender and age. Thus
	there was lesser increase in the WBC in Mediphope group,
	indicating a better prognosis, although statistically nonsignificant.
	There was earlier fall in temperature and Respiratory rate, higher
	rise in Spo2 levels in patients of Medihope group as compared to
	that of the Standard group. There was earlier relief from symptoms
	among the patients of Medihope group as compared to the Standard
	group.
	The outcomes were related to mean duration of hospital stay and
	changes in Chest X ray were comparable among the groups.
Conclusion	Medihope may be advocated in patients with mild and moderate
	severity patients of Corona infection along with Standard treatment
	as add on therapy for earlier mitigation of deranged temperature,
	Respiratory rate, WBC count, Spo2 levels and symptoms.

2. BACKGROUND

Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered coronavirus.

Most people infected with the COVID-19 virus were experience mild to moderate respiratory illness and recover without requiring special treatment. Older people and those with underlying medical problems like cardiovascular disease, diabetes, chronic respiratory disease, and cancer are more likely to develop serious illness.

The best way to prevent and slow down transmission is be well informed about the COVID-19 virus, the disease it causes and how it spreads. Protect yourself and others from infection by washing your hands or using an alcohol-based rub frequently and not touching your face.

The COVID-19 virus spreads primarily through droplets of saliva or discharge from the nose when an infected person coughs or sneezes, so it's important that you also practice respiratory etiquette (for example, by coughing into a flexed elbow).

At this time, there are no specific vaccines or treatments for COVID-19. However, there are many ongoing clinical trials evaluating potential treatments.

India on Monday 14th February 2021 registered 11,649 new coronavirus cases in the last 24 hours, taking the total tally to 1,09,16,589, according to the latest figures released by the Union Health Ministry. With this, a total of 1,06,21,220, who tested positive for the coronavirus, were discharged from the hospitals across the country after recovering from the infection so far. There are a total of 1,39,637 active cases.

A total of 82,85,295 people have been vaccinated against the Covid-19 in country ever since the mass inoculation drive began in January this year.

However, there has been a steady increase in number of patients of Covid-19 in Maharashtra in the second week of February 2021, causing alarm among the health official about the probability of second wave of pandemic as seen in European countries.

Ayurveda has enough potential and possibilities to be employed both for prevention and treatment of COVID-19. This were provide an important opportunity for learning and generating credible evidence. Participation of Ayurveda in addressing the COVID-19 challenge in India should not remain limited and seen as the extension of healthcare services and support to bio-medical system. Indeed, with adequate monitoring and data keeping during the implementation,

important lessons and research directions are likely to emerge on the management of increasingly frequent and virulent communicable diseases. Implementation of proposed action is likely to provide evidence-based insights strengthening the scope of Ayurveda beyond preventive health care and care for non-communicable diseases.

AYUSH system across the country has been put on alert for being called anytime to serve the nation. AYUSH healthcare facilities are also being readied to be converted into quarantine facilities in times of need. From this perspective, implementing the suggested intervention plan within AYUSH healthcare facilities by Ayurveda workforce may benefit the nation greatly. India is the country where the world's oldest living health care system originated and therefore it is being carefully watched by the world community forhow it handles the crisis using its own resources. China has done it. It is India's turn now to show its traditional healthcare might.

From the Ayurvedic point of view, COVID-19 is ajanapa-dodhwamsa vikara(epidemic disease).

The concept of an epidemicis described in Charaka Samhita: Vimana Sthana, Chapter 3."...even though there is dissimilarity in the physical constitution of human beings, still there are such factors which are common to all individuals and vitiation of these factors leads to the simultaneous manifestation of diseases having the same set of symptoms leading to the destruction of countries. Factors which are common for all the inhabitants of a country are air, water, location and seasons."[1,Vimana Sthana, 3/6]Janapadodhwamsa is a situation where the environment - air, water, land and seasons - is vitiated, causing a simultaneous manifestation of a disease among large populations (epidemic), destroying human habitations. In India there is precedence of treating the Chikungunya virus epidemic with Ayurveda and Siddha medicines [2]. However, there is no attempt in India to directly employ Ayurvedic medicines in the treatment of Corona virus disease. In this context, the present study is planned to evaluate the efficacy of "Medihope" in treatment of patients tested positive for Covid 19 infection.

Medihope is a patented product which consists of dry powder extract of

- 1. Lantana camara 35%
- 2. Tectona grandis35%
- 3. Murraya paniculata 10%
- 4. Terminalia paniculata 10%
- 5. Toddalia asiatica 05%

6. N. foetida 05%

Sr. No.	Medicinal Herbs	Medicinal Uses
1.	Lantana Camara	Studies conducted in India have found that Lantana leaves can display antimicrobial, fungicidal and insecticidal properties. L. camara has also been used in traditional herbal medicines for treating a variety of ailments, including cancer , skin itches, leprosy, rabies, chicken pox, measles, asthma and ulcers.
2.	Teak Wood	Virtually every part of the teak tree has medicinal uses , and medical science has shown that the leaves have antibacterial, anti-ulcer and antifungal properties . In Ayurdeva the wood is considered a laxative, a sedative for the uterus, good for piles, dysentery and leucoderma.
3.	Murraya Paniculata	Paniculata leaves extract is orally used to alleviate pain. In the Philippines, leaves were also used to treat diarrhea and dysentery because of their stimulant and astringent activities. In India, people sometimes used root bark of M. paniculata as remedy for coughs, hysteria and rheumatism.
4.	Terminalia Paniculata	Internally, the bark powder is used in treating Fever and diseases of Pitta and Kapha doshas. It reduces inflammation . Externally, It helps in Wound healing. It helps in faster healing of fractured bones. It acts as natural immunity booster.
5.	Todalia Asiatica	Toddalia asiatica is used medicinally by Venda herbalists. The fruit is used by the Massai as a cough remedy and the roots in the treatment of indigestion and influenza. The leaves are used for lung diseases and rheumatism.
6.	N. Foetida	It has been reported that extracts of N . foetida shows antibacterial activity. The methanol fractions were found to be most effective (Kumar et al., 2002). Camptothecin can be used as antimalarial drug because it affects erythrocytic malaria parasites in vitro (Bodley et al., 1998).

Medihope is an FDA approved Ayurvedic product whose individual components have been mentioned in

Ayurvedic texts. None of the individual components belongs to the Schedule E (1) of the Drugs and Cosmetics Act, 1940.

b. Safety/ toxicity studies & Biological activity

Medihope is a patented Ayurvedic product whose individual components have been mentioned in Ayurvedic texts. None of the individual components belongs to the Schedule E (1) of the Drugs and Cosmetics Act, 1940.

Rationale of the study: With ever increasing trend of number of people detected for Covid 19 infection, there is parallel increase in the number of deaths due to the disease in India. Although trials are ongoing with respect to prevention and cure of Covid 19 infection, no product has been approved for treatment of the disease.

Research Question:

What is the utility of Medihope as an add on therapy for Covid 19 patients?

Research hypothesis:

Medihope with standard treatment is more efficacious as compared to Standard treatment alone with respect to remission of Covid 19 infection

Null Hypothesis:

There is no difference between the efficacy of Medihope with standard treatment and Standard treatment alone with respect to remission of Covid 19 infection.

Study objectives

- Primary objective: To compare the efficacy of Is Medihope with standard treatment VS Standard treatment alone with respect to changes in SpO2 levels and X ray chest of COVID 19 positive patients admitted to Dedicated Covid Hospital, Loni and Swargiya Shrimati Sindhutai Vikhe Patil, Covid Care Center, Ahmednagar.
- 2. Secondary objective: To compare the efficacy of Is Medihope with standard treatment VS to Standard treatment alone with respect to changes in temperature, respiratory symptoms and change in CBC & Duration of stay of COVID 19 positive patients admitted to Dedicated Covid Hospital, Loni and Swargiya Shrimati Sindhutai Vikhe Patil, Covid Care Center, Ahmednagar.

MATERIAL AND METHODS

- A. Study design: Open labeled, Non-Randomized, Multicentric Phase III Clinical trial
- B. Study population: Patients infected with Covid 19 admitted and receiving treatment in Covid hospitals

Participant Inclusion Criteria

- 1. Covid-19 patients diagnosed by RTPCR/ Rapid test, wereing to participate and comply with all study procedures of the study.
- 2. Patients with or without history of Diabetes and/or Hypertension.
- 3. Patients wereing to give written informed consent.
- 4. Patients of age more than 18 years of either gender.
- 5. Patients with mild to moderate symptoms of Covid-19 infection.

Participant Exclusion Criteria

- 1. Patients with previous history of severe respiratory illness, viz Pneumonia, COPD.
- 2. Patients requiring Ventilatory support.
- 3. Pregnant and lactating women.
- 4. Patients with any other acute or chronic illness, viz Crohns disease, Congestive cardiac failure, rheumatoid arthritis, AIDS.
- 5. Patients receiving medication other than that for diabetes, hypertension.
- 6. Patients receiving any medication of traditional medicine.
- 7. Patients with history of allergy.
- 8. Patients with any psychiatric illness or history of drug abuse.

Withdrawal Criteria

Reasons for Withdrawal and handling of withdrawals

- 1. Deterioration of patient's health status.
- 2. Deterioration in laboratory and radiological parameters.
- 3. Development of adverse event.
- 4. Participant not wereing to continue the study.
- 5. The participant meets any exclusion criteria (either newly developed or not previously recognized).
- 6. Patient taking discharge against medical advice.

7. Patient referred to higher Covid Centre.

Handling of Withdrawals

The participants were followed until discharge. The standard treatment were continued. Participants requesting voluntary withdrawal were convinced by the Investigator to complete an end-of-study evaluation.

Method for taking Informed Consent (STANDARD TREATMENT PROTOCOL FOR COVID 19 Revision 4 by FDA Dated-22.07.2020):

The unsigned consent form is provided to the patient and reviewed via phone or Video conference. After receiving verbal confirmation by the patient, a photograph of the signed consent form can be sent to the investigator or designee and entered into the trial records.

Randomization and Blinding

The patients shall not be randomized. Being an open-labeled study, blinding was not required for the study. But the Radiologists and evaluating physician shall not be disclosed regarding the treatment unless necessary.

Study population: patients infected with Covid 19 admitted and receiving treatment in following Covid hospitals were included in the study:

- 1. Dedicated Covid Hospital, Loni and
- 2. Swargiya Shrimati Sindhutai Vikhe Patil, Covid Care Center, Ahmednagar.

The study population, after recruitment were divided into two categories, viz. Mild and Moderate, depending on requirement of oxygen treatment and assisted ventilation.

A. Mild category patients

State&	Group	Criteria
	Group A	Asymptomatic but positive forCOVID-19
	Group B	Symptomatic/URTI without comorbidity Fever Cough Sore throat Malaise
		Headache Anosmia* Loss of taste*
		Diarrhoea*
		*Can be only earliest presenting symptom.
		RED FLAG SIGNS (if developed likely to
Mild		deteriorate) 1.SpO2-<94% on room air
wind		2.Neutrophil Lymphocyte
	Group C	Symptomatic/URTI with
		comorbidity
		Obesity>60YrsDMHTN/IHD
		COPD/Chronic lung disease Immunocompromised state Immunosuppressive
		drugs CKD
		RED FLAG SIGNS (if developed likely to
		deteriorate) 1. Neutrophil Lymphocyte
		ratio>3.52.P:Fratiolessthan300
		3.THREE-minute walk test and on repeat pulse oximetry decreased SpO2 more than
		6% 4. Resting tachycardia
		5. Raised CRP/Sr. Ferritin/D-dimer/LDH/
		Triglycerides 6 SpO2-<94% on room air

B. Moderate category patients

State	Criteria
Moderate	 Pneumonia Adolescent or adult with presence of clinical features of dyspnea and or hypoxia, fever, cough, including SpO2<94% (range90-94%) on room air, Respiratory Rate more or equal to 24 per minute. RED FLAG SIGNS (if developed likely to deteriorate) 1. Neutrophil Lymphocyte ratio>3.5 2. P:F ratio less than300 3. Raised CRP/ Sr. Ferritin/ D-dimer/LDH/ Triglycerides 4. SpO2 less than 90% on room air

Therapy/ Procedure

The study participants were subjected to one of the following treatment options:

- 1. Standard treatment
- 2. Standard treatment + Medihope supplementation

1. Standard treatment: A. Mild category patients

State & (Group	Criteria	Investigations	Site of Admission	Treatment	Remarks
	Group A Group	Asymptomatic but positive for COVID- 19 Symptomatic/URTI	CBC, RFT, RBS, LFT, ECG	Isolation ward /Home isolation	Monitoring of patient	Patient to be followed up daily for temperature, vitals and
Mild	B	 without comorbidity Fever Cough Sore throat Malaise Headache Anosmia* Loss of taste* Diarrhoea* * Can be only earliest presenting symptom. RED FLAG SIGNS (if developed likely to deteriorate) 1.SpO2- <94% on room air 2. Neutrophil Lymphocyte ratio> 3.5 3. Resting tachycardia 	CBC, RFT, RBS, LFT, CXR, ECG, SpO2 monitoring by Pulse Oxymeter	Isolation ward/ Home isolation	Symptomatic Treatment such as Antipyretic, adequate nutrition and appropriate rehydration	Oxygen Saturation (SpO2) If develops any worsening symptoms (such as mental confusion, difficulty in breathing, persistent pain or pressure in the chest, bluish coloration of face/lips, dehydration, decreased urine output etc.), they should be immediately admitted

Group	Symptomatic/URTI	CBC, LFT	Isolation	A)	1. ECG -
С	with comorbidity	RFT, RBS	ward	Tab. HCQ 400mg BD	Baseline &
	Obesity	CXR, ABG		on day 1 then 200 mg	daily to look
	>60 Yrs	ECG		BD for 4 days	for QTc
	DM	ESR, CRP			prolongation
	HTN/IHD	LDH		OR	if patient is on
	COPD/Chronic	S. Ferritin			HCQ
	lung disease	D-dimer		Tab. Favipiravir 1800	2. If patient is
	Immunocompromi	If OTc		mg BD on day 1 followed by 800 mg	symptomatic
	sed state	n Q IC		BD for 7 days if	at day 5 also,
	Immunosuppressi	ECG then daily		needed can be	continue
	ve drugs	S. electrolyte		continued up to	therapy for
	CKD	ionic Calcium		maximum 14 days	additional 5
	KED FLAG SIGNS	& Magnesium		J	days
	(II developed likely to				
	deteriorate)			B) In: I MWH 40mg SC	
	1. Neutrophil			OD per day	
	Lymphocyte ratio >3.5			OD per day	
	2. P:F ratio less than			C) Antibiotics-	
	300			T. Cefixime 200 mg	
	3. THREE-minute			BD	
	walk test and on repeat			OR	
	pulse oximetry			T. Augmentin 625	
	decreased SpO2 more			TDS	
	than 0% A Posting techycordia			OR	
	5 Raised CRP/			To be given as per	
	Sr. Ferritin/			local antibiotic policy	
	D-dimer/LDH/				
	Triglycerides				
	6. SpO2- <94% on				
	room air				
			1		

B. Moderate category patients

Moder	Pneumonia	CBC, LFT	DCH	A)	1. ECG -
ate		RFT, RBS		Tab. HCQ 400 mg BD	Baseline &
	Adolescent or adult	CXR, ECG,		on day 1 then 200 mg	daily to look
	with presence of	ABG		BD for 5 days	for QTc
	clinical features of	ESR, CRP		OR	prolongation
	dyspnea and or	S. Ferritin		Inj Remdesivir	if patient is on
	hypoxia, fever, cough,	D-dimer/LDH		200 mg OD for day 1	HCQ
	including SpO2 <94%			& 100 mg OD for next	
	(range 90-94%) on	If QTc		4 days	2. If patient
	room air, Respiratory	prolongation in		OR	satisfies
	Rate more or equal to	ECG then daily		Tab. Favipiravir 1800	indication,
	24 per minute.	S. electrolytes		mg BD on day 1	then
		ionic calcium		followed by 800 mg	Tocilizumab/
		& Magnesium		BD for 7 days if	Itolizumab/
				needed can be	Convalescent
	RED FLAG SIGNS	Follow up		continued upto	Plasma can be
	(if developed likely to	CRP, D-dimer		maximum 14 days	given
	deteriorate)	& Sr. Ferritin		B)	(doses given
		every 48-72		Inj. LMWH 40mg SC	in newer
	1. Neutrophil	hours (if		OD per day	therapies
	Lymphocyte ratio >	available);			section)
	3.5	CBC with		C)	2 101100
	2. P:F ratio less than	DLC, Absolute		If SpO2 < 88% -	3. If HCQs
	300	lymphocyte		1) Consider CARP	cannot be
	3. Raised CRP/	count,		protocol	given for any
	Sr. Ferritin/	KF1/LF1 daily		protocor	contraindicati
	D-dimer/LDH/			2) Inj. MPS 0.5 to 1mg	on like
	1 Sin O2 less their			/kg /day for 3 days and	prolong Q1c
	4. SpO2 less than			if d dimer/Sr Ferritin	or in
	90% on room air			normal after 3 days,	knownGo PD
				oral Prednisolone	deficiency
				tapered dose for 5	of
				days	UI Ivormostin12
				OR Dexamethasone	mg oral single
				IV/Oral 6 mg OD for	dean l
				10 days	dose +
					100 m a DD
				D) Antibiotics:	for 5 days con
				Inj Ceftriaxone 1 g IV	he considered
				OD for 5-10 days.	be considered
				OR	
				To be	
				given as per	
				oral antibiotic	
				policy	

C. Severe Category patients.

Severe	Severe	CBC, LFT	Isolation	A)	1. ECG -
	Pneumonia/ARDS/Sep	RFT, RBS	ICU	Inj Remdesivir	Baseline &
	tic Shock/Sepsis	CXR, ECG,		200 mg OD on day 1	daily to look
		ABG		& 100 mg OD for next	for QTc
	Adolescent or adult:	ESR, CRP		4 days	prolongation
	with clinical signs of	S. Ferritin		OR	if patient is on
	Pneumonia plus one of	D-dimer		Tab. UCO 400 mg PD	HCQ
	the following;	LDH,		on day 1 then 200 mg	
	respiratory rate >30	S.		BD for 5 days with	2. Mechanical
	breatns/min, severe	Triglycerides		close monitoring	ventilation as
	sport comparison services serv			close monitoring	per CAPDenet
	sp02 <90% 0110011	Blood culture		B)	rotocol
	an.	& sensitivity		Inj. LMWH 40mg SC	protocor
		& sensitivity		OD per day (if some	
	RED FLAG SIGNS	If OTc		signs of bleeding seen	
		prolongation in		then to be stopped)	
	1. Neutrophil	ECG, then		IMD. If D. dimonia	
	Lymphocyte ratio >	daily S.		nvir. II D-uiiiler is	
	3.5	electrolytes		I MWH to be given in	
	2. Raised	ionic calcium		therapeutic dose i e 40	
	CRP/Ferritin/D-	& S.		mg SC BD.	
	dimer/LDH/Triglyceri	Magnesium			
	des/Troponin I /CPK-	_		C)	
	MB	If QTc>500ms		Inj. MPS 0.5 to 1 mg	
		HCQ should be		/kg /day for 5-7 days	
		avoided		and to be extended	
				depending upon	
				followup D dimer	
				OR	
				Dexamethasone	
				IV/Oral	
				6 mg OD for 10 days	
				D)	
				D)	
				indication then	
				Tocilizumab/	
				Itolizumah/	
				Convalescent Plasma	
				can be given (doses	
				given in newer	
				therapies section)	
				E) Antibiotics:	
				Inj. Meropenem 1 g IV	
				TDS extended	
				infusion over 30 min.	
				OK ANUDIOLICS to be	
				given as per local	
				antioione poney	

*If any investigation is not available at treating hospital, it may be outsourced.

<u>Note:</u> In addition, drugs may be given to improve immunity and possibly reduce viral replication. Zinc 50 mg BD, Vitamin C 500 mg BD, Vitamin A, Vitamin D, Magnesium Sulphate

2. Medihope:

The above treatment as per Category of the patients with 1 scoop of medicine (6 grams) mixed in

1 glass of water twice in a day after Breakfast and after Dinner for 7 days in Mild Category

patients and 15 days in Moderate Category patients.

SpO2 levels, Changes in respiratory Signs and Symptoms and Adverse event were evaluated by a single treating physician.

After enrollment of the patients, following investigations were performed (As per ICMR guidelines):

- 1. SpO2 levels,
- 2. Temperature,
- 3. Respiratory symptoms
- 4. CBC

All study participants were subjected to daily clinical evaluation and pulse oximetry for SpO2

Following investigations were performed on completion of treatment (7 days):

- 1. SpO2 levels,
- 2. Temperature,
- 3. Respiratory symptoms
- 4. CBC
- 5. Status at discharge

Statistical Analysis

Data were entered in MS-Excel worksheets & Statistical analysis was conducted in SPSS version 21. Descriptive summary of sociodemographic characteristics and outcome measures were provided for all trial participants at baseline and at the time of discharge. This included means and standard deviation or proportion. The primary analysis were intention -to-treat.Normality were tested using Kolmogorov-Smirnov test. The quantitative variables showing normal distribution were described using Mean and Standard deviation (SD) whereas skewed data were described using Median and Inter-quartile range (IQR). Test of significance like Paired T test, Wicoxon, Repeated measures/One-way ANOVA were used. Predictions were done multiple regression analysis. A value of p<0.05 were considered statistically significant.

RESULTS:

In the present study, 256 patients were recruited.

Study center	Number of patients	Percent
CCC	89	34.8
DCH	167	65.2
Total	256	100.0

Table no. 1. Distribution of patients according to Study center.

CCC- Covid Care Center, Ahmednagar, DCH- Dedicated Covid Hospital, Loni



89 patients (34.6%) were recruited from Swargiya Shrimati Sindhutai Vikhe Patil, Covid Care Center, Ahmednagar, while 167 patients (65.2%) were recruited from Dedicated Covid Hospital, Loni.

Gender	Number of patients	Percent
Male	162	63.3
Female	94	36.7
Total	256	100.0

Table no. 2. Distribution of patients with respect to gender.



Of the 256 patients, majority of patients were Males (162, 63.3%) as compared to Females (36.7%).

Gender	Mean age (years)	Standard deviation		
Male	44.73	16.45		
Female	43.20	17.00		
P=0.47, Unpaired t test				

Table no. 3. Mean age of patients with respect to Gender.



The mean age of Males and Females was 44.73 ± 16.45 and 43.20 ± 17.00 years, respectively (Table no. 3)

Sr. No.	Age Groups (Years)	CCC	DCH	Total
1.	≤ 20	02	11	13
2.	21 - 30	10	50	60
3.	31 – 40	11	26	37
4.	41 - 50	15	32	47
5.	51 - 60	24	36	60
6.	61 - 70	19	09	28
7.	71 - 80	06	03	09
8.	≥ 81	02	00	02
	Total	89	167	256

Table No. 4. Age wise distribution of the patients as per center

CCC- Covid Care Center, Ahmednagar, DCH- Dedicated Covid Hospital, Loni

0



Figure No. 4. Age wise distribution of the patients as per center

Table no. 4 represents age wise distribution of the patients as per center. Overall, most of the patients belonged to 21-30 and 51-60 years age group (60, 23.43% each) followed by 41 - 50 (47, 18.35%) and 31-40 (37, 14.45%) years.

≤ 20 21 - 30 31 - 40 41 - 50 51 - 60 61 - 70 71 - 80 ≥ 81 Age group (Years)

With respect to Center, most of the patients of from Dedicated Covid Hospital, Loni, belonged to age group of 21-30 years (50, 29.9%) followed by 51-60 (36, 21.55%) and 41-50 years (32, 19.16%), while most of the patients from Covid Care Center, Ahmednagar belonged to 51-60 (24, 26.96%), followed by 61 - 70 (19, 21.34%), 41 – 50 years (15, 16.85%).

Sr. No.	Age Groups (Years)	Female	Male	Total (%)	
1.	≤ 20	05	08	13	
2.	21 - 30	39	21	60	
3.	31 - 40	22	15	37	
4.	41 - 50	34	13	14	
5.	51 - 60	34	26	60	
6.	61 - 70	21	07	28	
7.	71 - 80	06	03	09	
8.	≥ 8 1	01	01	02	
	Total	162	94	256	
Chi-square (χ2) test: 8.39 df:07 P:0.29# Cramers'V:1.81					
	Mean age \pm Sd	44.73 ± 16.4	43.20 ± 17.0		
	Range	18.0-81.0	19.0-89.0		

Table No. 5. Age and Gender wise distribution of the patients

Figure No. 5. Age and Gender wise distribution of the patients



Table no. 5 represents Age and Gender wise distribution of the patients. Most of the Female patients belonged to age group of 21-30 (39, 24.07%) followed by 41-50 and 51-60 (34, 20.98% each). In Male patients, the most common age group was 51-60 (26, 27.65%) followed by 31-40 (15, 15.95%) and 41-50 years (13, 13.82%). There was no statistically significant variation between males and females with respect to their age groups.

	8 8	-	-
Sr. No.	Age Groups (Years)	STD	STD-MED
1.	≤ 20	09	04
2.	21 - 30	25	35
3.	31 - 40	21	16
4.	41 – 50	26	21
5.	51 - 60	29	31
6.	61 – 70	16	12
7.	71 - 80	01	08
8.	≥ 81	01	01
	Total	128	128
	Chi-square (χ2) test: 10.88 df:	07 P:0.14# Cramers'V	/:0.206
	Mean age ± Sd	43.78 ± 16.10	44.55 ± 17.21
	Range	18.0-89.0	19.0-81.0

 Table No 6. Age and Treatment groups distribution of the patients

Figure No 6. Age and Treatment groups distribution of the patients



Table no 6. displays Age and Treatment groups distribution of the patients. Most of the patients in Standard group belonged to 51-60 (29, 22.65%) followed by 41-50 (26, 20.31%) years, while most of the patients in Standard with Medihope belonged to 21-30 (35, 27.34%) followed by 51-60 (31, 24.21%) years. There was no statistically significant variation between treatment groups with respect to their age groups.

History of hypertension	Number of patients	Percent
Absent	206	80.5
Present	50	19.5
Total	256	100.0

Table no. 7. Distribution of patients with respect to history of hypertension.

Figure no. 7. Distribution of patients with respect to history of hypertension.



As shown in Table no. 7, 50 patients (19.5%) reported history of hypertension, while 206 (80.5%) patients had no history of hypertension.

History of Diabetes	Number of patients	Percent
Absent	219	85.5
Present	37	14.5
Total	256	100.0

Table no. 8. Distribution of patients with respect to history of Diabetes.

Figure no. 8. Distribution of patients with respect to history of Diabetes.



As shown in Table no. 8, 37 patients (14.5%) reported history of diabetes, while 219 (85.5%) patients had no history of diabetes.

Category	Number of patients	Percent
Mild Group A	75	29.3
Mild Group B	106	41.4
Mild Group C	25	9.8
Moderate	50	19.5
Total	256	100

Table no. 9. Distribution of patients with respect to Category of Covid infection at admission.

Figure no. 9. Distribution of patients with respect to Category of Covid infection at admission.



Table no. 9 displays distribution of patients with respect to Category of Covid infection at admission. Most of the patients belonged to Mild Group B (106, 41.4%) followed by Mild Group A (75, 29.3%).

Treatment Group	Number of patients	Percent	
Standard	128	50	
Standard + Medihope	128	50	
Total	256	100	

Table No. 10a. Distribution of patients with respect to Treatment groups.

Figure No. 10a. Distribution of patients with respect to Treatment groups.



Table no. 10a displays distribution of patients with respect to Treatment groups. The patients were equally distributed in both '**Standard' and 'Standard + Medihope group'.**

Treatment Group	ST	Ď	STD-	MED	То	tal
Disease severity	Frequency	Percent	Frequency	Percent	Frequency	Percent
A_Mild	37	28.9	38	29.7	75	29.30
B_Mild	55	43.0	51	39.8	106	41.41
C_Mild	7	5.5	18	14.1	25	9.77
Mod	29	22.7	21	16.4	50	19.53
Total	128	100	128	100	256	100

Table No. 10b. Distribution of patients with respect to Treatment groups and severity of disease.

Figure No. 10b. Distribution of patients with respect to Treatment groups and severity of disease.



Table 10b and Figure 10b represent distribution of patients with respect to Treatment groups and severity of disease. Mild B group was the most common severity found in both treatment groups.

Sr. No.	Gender	STD	STD-MED	Total (%)
1.	Male	78	84	162
2.	Female	50	44	94
	Total	128	128	256
	Fishers Exact Test 0.51#			

Table No 11: Gender and Treatment groups distribution of the patients

Figure No 11: Gender and Treatment groups distribution of the patients



The above table shows gender and treatment groups distribution of the patients. There was no statistically significant difference observed in treatment groups with respect to gender.

Day	Temperature					
	Mean	Standard deviation	Minimum	Maximum		
1	98.4	0.82	97	101		
2	98.32	1.04	88	101		
3	98.11	0.504	97	101		
4	98.09	0.41	97	100		
5	97.92	0.39	96	99		
6	97.96	0.42	97	99		
7	97.95	0.41	96	99		

Table no. 12. Mean Temperature of patients with respect to day of inclusion in the study





There was a decreasing trend of body temperature found in the patients.

Day	Spo2 level				
	Mean	Standard deviation	Minimum	Maximum	
1	94.7	4.34	80	99	
2	94.94	4.31	80	99	
3	95.30	3.94	82	99	
4	95.82	3.31	83	99	
5	96.33	2.40	88	99	
6	96.06	5.62	16	99	
7	96.80	2.05	84	99	

Table no. 13. Mean Spo2 levels of patients with respect to day of inclusion in the study





There was an increasing trend of Mean Spo2 levels found in the patients.

Day	Respiratory rate					
	Mean	Standard deviation	Minimum	Maximum		
1	19.23	4.68	14	30		
2	19.11	4.60	15	30		
3	18.51	3.60	14	30		
4	18.14	3.09	15	32		
5	17.94	2.65	15	24		
6	18.12	5.63	15	98		
7	17.77	2.71	15	31		

Table no. 14. Mean Respiratory rate of patients with respect to day of inclusion in the study




There was a decreasing trend of Respiratory rate found in the patients.

	WBC		Lymphocytes		Monocytes	
	Baseline	Discharge	Baseline	Discharge	Baseline	Discharge
Mean	6530.60	7478.57*	26.54	29.14#	7.17	6.32 ^{\$}
Std. Deviation	2563.72	3001.82	12.12	15.87	3.13	2.52
Minimum	2010.0	2760.0	3.0	2.0	1.0	1.0
Maximum	16500.0	26740.0	86.0	194.0	19.0	17.0

Table no. 15. WBC count of patients

*P<0.0001, vs Baseline, Paired t test

[#]P=0.037, vs Baseline, Paired t test

^{\$}P=0.0008, vs Baseline, Paired t test



Figure no. 15b. Lymphocyte and Monocyte count of patients



An increase in WBC count and Lymphocyte count was observed, while there was decrease in Monocyte count.

Table no. 16. Serum Urea and Serum Creatinine of patients

	Serum	Urea	Serum Creatinine		
	Baseline	Discharge	Baseline	Discharge	
Mean	29.92	29.98*	0.97	$0.88^{\#}$	
Std. Deviation	28.58	14.86	1.042	0.80	
Minimum	9.0	10.0	.10	.4	
Maximum	304.4	140.0	8.88	8.0	

*P<0.97, vs Baseline, Paired t test

[#]P=0.27, vs Baseline, Paired t test





There was no significant change in the Serum urea and Serum Creatinine of the patients before and after treatment.

Table no. 17. Whole Blood Cell Count, Differential count, Serum Urea and Serum Creatinine of patients with respect to treatment group

Variables	STD		P^	STD	_MED	P^
(Mean ± SD)	Baseline	Discharge		Baseline	Discharge	
WBC	6682.91±2454	7845.24±3431	0.00*	6378.29±2669.0	7111.89±2459.68	0.001*
Lympho.	27.11±11.38	28.79±11.68	0.08*	25.97±12.83	29.49±19.22	0.05*
Mono.	07.34±3.02	6.42±2.47	0.00*	7.00±3.24	6.23±2.59	0.005*
Eosino.	2.47±5.59	2.33±2.15	0.78#	1.61±1.78	2.00±1.92	0.009*
Hb	13.23±2.25	13.55±2.28	0.68#	13.27±2.01	13.34±1.82	0.64#
PC	201.50±120.65	230.00±132.00	0.00*	144.78±111.29	167.19±125.46	0.00*
Sr. Urea	30.90±37.28	30.24±17.63	0.75#	28.95±15.75	29.72±11.51	0.49#
Sr. Creat	0.98±1.37	0.86±0.73	0.03*	0.96±0.94	0.90±0.85	0.007*
		Paired T San	nple Sta	tistics		

















On intra group comparison of the WBC count, differential count, Hemoglobin levels, Platelet count, Serum Urea and Serum Creatinine levels during baseline and seventh day in the Standard and Medihope group, all parameters except Hemoglobin, Serum Urea, Platelet count in both groups and Eosinophil count in Standard group were statistically significantly different.

Trt.GRP	Temp	Mean	Std.	95% Confid	ence Interval	Р
	DAY		Error	Lower	Upper	Wilks Lambda
				Bound	Bound	
STD	1	98.460	.075	98.312	98.609	
	2	98.438	.078	98.285	98.592	
	3	98.105	.041	98.024	98.187	
	4	98.088	.035	98.018	98.157	0.000*
	5	97.906	.030	97.846	97.966	
	6	97.977	.036	97.906	98.048	
	7	97.953	.033	97.888	98.018	
STDMED	1	98.436	.072	98.294	98.578	
	2	98.210	.104	98.004	98.416	
	3	98.128	.048	98.034	98.223	
	4	98.088	.038	98.013	98.162	0.000*
	5	97.939	.038	97.864	98.014	
	6	97.948	.039	97.870	98.025	
	7	97.961	.041	97.881	98.041	
			Repea	ted Measure	ANOVA	

 Table 18: Day wise comparison of mean temperature in Treatment groups

Figure 18: Day wise comparison of mean temperature in Treatment groups



There was a decreasing trend in the temperature in both treatment groups, but there was rapid fill in temperature on second day of treatment in Medihope group as compared to Standard group.

TrtGRP	Spo2	Mean	Std.	95% Confid	ence Interval	Р
	DAY		Error	Lower	Upper	Wilks Lambda
				Bound	Bound	
STD	1	94.625	.391	93.851	95.399	
	2	94.617	.401	93.823	95.411	
	3	95.031	.375	94.289	95.773	
	4	95.648	.321	95.013	96.284	0.000*
	5	96.180	.235	95.715	96.644	
	6	96.227	.241	95.751	96.703	
	7	96.711	.194	96.328	97.094	
STDME	1	94.883	.379	94.133	95.632	
D	2	95.266	.360	94.554	95.978	
	3	95.578	.319	94.947	96.210	
	4	95.992	.262	95.473	96.511	0.000*
	5	96.484	.187	96.114	96.855	
	6	96.598	.662	94.588	97.209	
	7	96.898	.168	96.566	97.231	
			Repe	ated Measures	ANOVA	

Table 19: Day wise comparison of Spo2 levels in Treatment groups

Figure 19: Day wise comparison of Spo2 levels in Treatment groups



There was an increasing trend in the Spo2 levels in both treatment groups, but the mean Spo2 levels of Medihope group were consistently higher when compared to Standard group.

TrtGRP	RR_Da	Mean	Std.	95% Confidence Interval		Р		
	У		Error	Lower	Upper	Wilks Lambda		
				Bound	Bound			
	1	19.305	.419	18.476	20.133			
	2	19.180	.415	18.358	20.002			
	3	18.578	.326	17.933	19.224			
STD	4	18.195	.277	17.647	18.743	0.000*		
	5	17.984	.233	17.523	18.446			
	6	17.875	.240	17.400	18.350			
	7	17.867	.257	17.358	18.376			
	1	19.156	.412	18.342	19.971			
	2	19.031	.399	18.241	19.822			
	3	18.438	.312	17.820	19.055			
STDMED	4	18.094	.271	17.558	18.629	0.000*		
	5	17.891	.237	17.422	18.359			
	6	17.667	.664	17.054	19.680			
	7	17.680	.222	17.240	18.119			
	Repeated Measures ANOVA							

 Table 20: Day wise comparison of Respiratory rate in Treatment groups

Figure 20: Day wise comparison of Respiratory rate in Treatment groups



There was a decreasing trend in the Respiratory rate in both treatment groups, but the mean RR was consistently lower in the Medihope group when compared with Standard group.

 Table 21: Comparison of change in mean temperature, Spo2 and Respiratory rate at discharge with respect to first day between the treatment groups

Difference 1 st days and 7 ^h day	STD-MED	STD	T test	Mann-Whitney U
ТЕМР	0.47 ± 0.98	0.50±1.01	t=25, df:254,P:0.79#	P: 0.81#
Spo2	-2.01±4.32	-2.085±4.33	t=0.13, df:254, P:0.89	P:0.29#
RR	1.47±3.43	1.43±3.78	t:0.08, df:254, P:0.93	P:0.74#
WBC	-733.60±2520.05	-1162.32±2939.71	t: 1.25, df:254,	P:0.53#











On comparing the difference between the baseline and Day 7 values of Standard group vs Medihope group, the temperature difference in the Medihope group was larger, however, it was statistically insignificant. Similarly the difference of Spo2 levels was larger in Medihope group, but not statistically significant. The difference in the WBC count and Respiratory rate were statistically comparable.

	1 st Day	7 th Day	Paired test	Wilcoxon Test
STD Group	98.46±0.84	97.95±0.37	t:5.63, df:127,P: 0.00*	P:0.000*
STD MED Group	98.43±0.81	97.96±0.45	t:5.45, df:127, P:0.000*	P:0.000*

Table 22: Comparison of mean temperature on Day 1 and Day 7 between the treatment groups

Figure 22: Comparison of mean temperature on Day 1 and Day 7 between the treatment groups



On comparing the mean temperature on Day 1 and Day 7 between the treatment groups, there was statistically significant reduction in both groups.

Table 23. Com	narison of mean	Sno2 on Da	v 1 and Dav 7 he	ween the treatment grou	ing
1 abic 25. Com	parison or mean	Spoz on Da	y I anu Day 7 DC	ween me neannent grou	the

	1 st Day	7 th Day	Paired test	Wilcoxon Test
STD Group	94.62±4.42	96.71±2.19	t:-5.44, df:127, P:0.00*	P:0.000*
STD MED Group	94.88±4.28	96.89±1.90	t:-5.27, df:127,P:0.000*	P:0.000*

Figure 23: Comparison of mean Spo2 on Day 1 and Day 7 between the treatment groups



On comparing the mean Spo2 levels on Day 1 and Day 7 between the treatment groups, there was statistically significant increase in both groups.

	1 st Day	7 th Day	Paired test	Wilcoxon Test
STD Group	19.30±4.73	17.87±2.19	t:4.29, df:127, P:0.000*	P:0.000*
STD MED Group	19.16±4.65	17.68±2.51	t:4.85, df:127, P:0.000*	P:0.000*

Table 24: Comparison of mean Respiratory rate on Day 1 and 7 between the treatment groups

Figure 24: Comparison of mean Respiratory rate on Day 1 and 7 between the treatment groups



On comparing the mean Respiratory rate on Day 1 and Day 7 between the treatment groups, there was statistically significant reduction in both groups.

	STD	STDMED				
Days (Mean± SD)	6.67 ±1.19	6.97 ± 1.71				
Mann-Whitney U Test: 0.09 Non significant						

Table 25: Comparison of mean stay in hospital between the treatment groups



There was no difference observed in the mean stay in hospital between the treatment groups.

Table 25: Comparison of changes in Xray Chest report of patients before and after treatment.

STD group		
Before treatment	Haziness	23
	Normal	60
After treatment	Regression	23
	Normal	60
STD MED group		
Before treatment	Haziness	30
	Normal	54
After treatment	fter treatment Regression	
	Normal	54

All patients in the study, irrespective of the treatment allotted, showed improvement in X-ray chest finding with respect to reduction in haziness of the chest fields. Patients with normal report showed no change in the report after treatment.

Table 26: Day wise presence of symptoms of Cough, Sore throat, Malaise, Dyspnea and										
	Headache among patients of treatment groups									
Day/Treatment	Co	ugh	Sore	throat	Ma	laise	Dys]	pnea	Head	lache
group	STD	MED	STD	MED	STD	MED	STD	MED	STD	MED
Day 1	76	86	59	62	49	65	29	46	28	36
Day 2	78	86	58	54	48	53	35	33	30	28
Day 3	58	66	40	36	29	34	20	24	19	17
Day 4	44	52	17	21	10	21	18	22	15	11
Day 5	33	31	7	8	7	8	16	17	13	7
Day 6	32	21	2	3	2	6	4	4	7	4
Day 7	25	18	2	3	2	3	1	2	5	3

Figure 26a: Day wise presence of Cough among patients of treatment groups



The number of patients with complaint of Cough was greater in the Medihope group. There number of patient with cough in both groups were equal in both treatment groups on 5^{th} day, while the number was further lower in Medihope group on 6^{th} and 7 day of treatment.



Table 26b: Day wise presence of Sore throat among patients of treatment groups

The number of patients with complaint of Sore throat was greater in the Medihope group. There was steep decline in the number of patient with Sore throat in Medihope group on Day 2 and 3, while the number on day 4 was lower in Standard group and the numbers were equal in both treatment groups on Day 5, Day 6 and Day 7.



Figure 26c: Day wise presence of Malaise among patients of treatment groups

The number of patients with complaint of Malaise was greater in the Medihope group. There was steep decline in the number of patient with Malaise from Day 2, while the decline was observed on Day 3 in Standard group.



Table 26d: Day wise presence of symptoms of Dyspnea among patients of treatment groups

The number of patients with complaint of Dyspnea was greater in the Medihope group. There was steep decline in the number of patient with Dyspnea from Day 2, while there was an increase in Standard group on day 2 followed by fall in number on subsequent days.

Figure 26e: Day wise presence of Headache among patients of treatment groups



The number of patients with complaint of Headache was greater in the Medihope group. There was steep decline in the number of patient with Headache from Day 2, while there was an increase in Standard group on day 2 followed by fall in number on subsequent days. The number of patients were consistently lower in the Medihope group as compared to Standard group.

	Co	Total (%)		
Trt. Grps.	No	Yes		
STD	52(20%)	76 (30%)	128 (50%)	
STDMED	42 (16%)	86 (34%)	128 (50%)	
Total	94 (37%)	162 (63%)	256 (100%)	
Fisher's Exact Test; 0.12#				

Table 27: Cough at Day 1 among the patients with respect to treatment group

Figure 27: Cough at Day 1 among the patients with respect to treatment group



The difference in the number of patients with complaints of Cough on Day 1 between treatment groups was statistically insignificant.

	Sore	Total (%)		
Trt. Grps.	No	Yes		
STD	69 (27%)	59 (23%)	128 (50%)	
STDMED	66 (26%)	62 (24%)	128 (50%)	
Total	135	121	256 (100%)	
Fisher's Exact Test: 0.40#				

Table 28: Sore Throat at Day 1 among the patients with respect to treatment group

Figure 28: Sore Throat at Day 1 among the patients with respect to treatment group



The difference in the number of patients with complaints of Sore throat on Day 1 between treatment groups was statistically insignificant.

	Ma	Total (%)		
Trt. Grps.	No	Yes		
STD	79 (31%)	49 (19%)	128 (50%)	
STDMED	63 (25%)	65 (25%)	128 (50%)	
Total	142 (55%)	114 (45%)	256(100%)	
Fisher's Exact Test 0.02*				

Table 29: Malaise at Day 1 among the patients with respect to treatment group

Figure 29: Malaise at Day 1 among the patients with respect to treatment group



	Dys	Total (%)		
Trt. Grps.	No	Yes		
STD	99 (39%)	29 (11%)	128 (50%)	
STDMED	82 (32%)	46 (18%)	128 (50%)	
Total	181 (71%)	75 (29%)	256(100%)	
Fisher's Exact Test; 0.01*				

Table 30: Dyspnea at Day 1 among the patients with respect to treatment group

Figure 30: Dyspnea at Day 1 among the patients with respect to treatment group



The number of patients with complaints of Malaise and Dyspnea on Day 1 were higher in Medihope group as compared to Standard group.

	Head	Total (%)		
	1104		10tal (70)	
Trt. Grps.	No	Yes		
STD	100 (39%)	28 (11%)	128 (50%)	
STDMED	92 (36%)	36 (14%)	128 (50%)	
Total	192 (75%)	64 (25%)	256(100%)	
Fisher's Exact Test 0.15#				

Table 31: Headache at Day 1 among the patients with respect to treatment group

Figure 31: Headache at Day 1 among the patients with respect to treatment group



The difference in the number of patients with complaints of Headache on Day 1 between treatment groups was statistically insignificant.

	Co	Total (%)		
Trt. Grps.	No	Yes		
STD	50 (20%)	78 (30%)	128 (50%)	
STDMED	42 (16%)	86 (34%)	128 (50%)	
Total	92 (36%)	164 (64%)	256 (100%)	
Fisher's Exact Test 0.18#				

Table 32: Cough at Day 2 among the patients with respect to treatment group

Figure 32: Cough at Day 2 among the patients with respect to treatment group



	Sore	Total (%)		
The Charles	Bore	T III Oat	10tal (70)	
Irt. Grps.	NO	Yes		
STD	70 (27%)	58 (23%)	128 (50%)	
STDMED	74 (29%)	54 (21%)	128 (50%)	
Total	144 (56%)	112 (44%)	256 (100%)	
Fisher's Exact Test 0.35#				

 Table 33: Sore Throat at Day 2 among the patients with respect to treatment group

Figure 33: Sore Throat at Day 2 among the patients with respect to treatment group



	• •	<u> </u>	0 1	
	Ma	Total (%)		
Trt. Grps.	No	Yes		
STD	80 (31%)	48 (19%)	128 (50%)	
STDMED	75 (29%)	53 (21%)	128 (50%)	
Total	155 (61%)	101 (39%)	256 (100%)	
Fisher's Exact Test 0.30#				

Table 34: Malaise at Day 2 among the patients with respect to treatment group





	Dys	Total (%)			
Trt. Grps.	No	Yes			
STD	93 (36%)	35 (14%)	128 (50%)		
STDMED	95 (37%)	33 (13%)	128 (50%)		
Total	188 (73%)	68 (27%)	256 (100%)		
Fisher's Exact Test 0.44#					

Table 35: Dyspnea at Day 2 among the patients with respect to treatment group

Figure 35: Dyspnea at Day 2 among the patients with respect to treatment group



	Head	Total (%)		
Trt. Grps.	No	Yes		
STD	98 (38%)	30 (12%)	128 (50%)	
STDMED	100 (39%)	28 (11%)	128 (50%)	
Total	198 (77%)	58 (23%)	256 (100%)	
Fisher's Exact Test 0.44				

Table 36: Headache at Day 2 among the patients with respect to treatment group

Figure 36: Headache at Day 2 among the patients with respect to treatment group



	Cough		Total (%)
Trt. Grps.	No	Yes	
STD	70 (27%)	58 (23%)	128 (50%)
STDMED	62 (24%)	66 (26%)	128 (50%)
Total	132 (52%)	124 (48%)	256 (100%)
Fisher's Exact Test: 0.19#			

Table 37: Cough at Day 3 among the patients with respect to treatment group

Figure 37: Cough at Day 3 among the patients with respect to treatment group



	, 8	1 1	01
	Sore Throat		Total (%)
Trt. Grps.	No	Yes	
STD	88 (34%)	40 (16%)	128 (50%)
STDMED	92 (36%)	36 (14%)	128 (50%)
Total	180 (70%)	76 (30%)	256 (100%)
Fisher's Exact Test: 034#			

 Table 38: Sore Throat at Day 3 among the patients with respect to treatment group





The number of patients with complaints of Sore throat on Day 3 were statistically higher in Standard group as compared to Medihope group.

	Malaise		Total (%)
Trt. Grps.	No	Yes	
STD	99 (39%)	29 (11%)	128 (50%)
STDMED	94 (37%)	34 (13%)	128 (50%)
Total	193 (75%)	63 (25%)	256 (100%)
Fisher's Exact Test: 0.28			

Table 39: Malaise at Day 3 among the patients with respect to treatment group

Figure 39: Malaise at Day 3 among the patients with respect to treatment group



	Dyspnea		Total (%)
Trt. Grps.	No	Yes	
STD	108 (42%)	20 (08%)	128 (50%)
STDMED	104 (41%)	24 (09%)	128 (50%)
Total	212 (83%)	44 (17%)	256 (100%)
Fisher's Exact Test: 0.30#			

Table 40: Dyspnea at Day 3 among the patients with respect to treatment group

Figure 40: Dyspnea at Day 3 among the patients with respect to treatment group



	Headache		Total (%)
Trt. Grps.	No	Yes	
STD	109 (43%)	19 (07%)	128 (50%)
STDMED	111 (43%)	17 (07%)	128 (50%)
Total	220 (86%)	36 (14%)	256 (100%)
Fisher's Exact Test 0.42#			

Table 41: Headache at Day 3 among the patients with respect to treatment group

Figure 41: Headache at Day 3 among the patients with respect to treatment group


	Cough		Total (%)
Trt. Grps.	No	Yes	
STD	84 (33%)	44 (17%)	128 (50%)
STDMED	76 (30%)	52 (20%)	128 (50%)
Total	160 (63%)	96 (38%)	256 (100%)
Fisher's Exact Test 0.18#			

Table 42: Cough at Day 4 among the patients with respect to treatment group

Figure 42: Cough at Day 4 among the patients with respect to treatment group



	Sore Throat		Total (%)	
Trt. Grps.	No	Yes		
STD	111 (43%)	17 (07%)	128 (50%)	
STDMED	107 (42%)	21 (08%)	128 (50%)	
Total	218 (85%)	38 (15%)	256 (100%)	
Fisher's Exact Test 0.29#				

Table 43: Sore Throat at Day 4 among the patients with respect to treatment group

Figure 43: Sore Throat at Day 4 among the patients with respect to treatment group



	Malaise		Total (%)	
Trt. Grps.	No	Yes		
STD	118 (46%)	10 (04%)	128 (50%)	
STDMED	107 (42%)	21 (08%)	128 (50%)	
Total	225 (88%)	31 (12%)	256 (100%)	
Fisher's Exact Test 0.02*				

Table 44: Malaise at Day 4 among the patients with respect to treatment group

Figure 44: Malaise at Day 4 among the patients with respect to treatment group



The difference in the number of patients with complaints of Malaise on Day 4 between treatment groups was statistically significant (higher in Medihope group).

	Dyspnea		Total (%)	
Trt. Grps.	No	Yes		
STD	110 (43%)	18 (07%)	128 (50%)	
STDMED	106 (41%)	22 (09%)	128 (50%)	
Total	216 (84%)	40 (16%)	256 (100%)	
Fisher's Exact Test 0.30#				

Table 45: Dyspnea at Day 4 among the patients with respect to treatment group

Figure 45: Dyspnea at Day 4 among the patients with respect to treatment group



	Head	Total (%)		
Trt. Grps.	No	Yes		
STD	113 (44%)	15 (06%)	128 (50%)	
STDMED	117 (46%)	11 (04%)	128 (50%)	
Total	230 (90%)	26 (26%)	256 (100%)	
Fisher's Exact Test 0.26#				

Table 46: Headache at Day 4 among the patients with respect to treatment group

Figure 46: Headache at Day 4 among the patients with respect to treatment group



	Cough		Total (%)	
Trt. Grps.	No	Yes		
STD	95 (37%)	33 (13%)	128 (50%)	
STDMED	97 (38%)	31 (12%)	128 (50%)	
Total	192 (75%)	64 (25%)	256 (100%)	
Fisher's Exact Test 0.44#				

Table 47: Cough at Day 5 among the patients with respect to treatment group

Figure 47: Cough at Day 5 among the patients with respect to treatment group



	Sore Throat		Total (%)	
Trt. Grps.	No	Yes		
STD	121 (47%)	07 (03%)	128 (50%)	
STDMED	120 (47%)	08 (03%)	128 (50%)	
Total	241 (94%)	15 (06%)	256 (100%)	
Fisher's Exact Test 0.5#				

Table 48: Sore Throat at Day 5 among the patients with respect to treatment group

Figure 48: Sore Throat at Day 5 among the patients with respect to treatment group



	Malaise		Total (%)	
Trt. Grps.	No	Yes		
STD	121 (47%)	07 (03%)	128 (50%)	
STDMED	120 (47%)	08 (03%)	128 (50%)	
Total	241 (94%)	15 (06%)	256 (100%)	
Fisher's Exact Test 0.5#				

Table 49: Malaise at Day 5 among the patients with respect to treatment group

Figure 49: Malaise at Day 5 among the patients with respect to treatment group



	Dyspnea		Total (%)	
Trt. Grps.	No	Yes		
STD	112 (44%)	16 (06%)	128 (50%)	
STDMED	111 (43%)	17 (07%)	128 (50%)	
Total	223 (87%)	33 (13%)	256 (100%)	
Fisher's Exact Test 0.5#				

Table 50: Dyspnea at Day 5 among the patients with respect to treatment group

Figure 50: Dyspnea at Day 5 among the patients with respect to treatment group



	Headache		Total (%)	
Trt. Grps.	No	Yes		
STD	115 (45%)	13 (05%)	128 (50%)	
STDMED	121 (47%)	07 (03%)	128 (50%)	
Total	236 (92%)	20 (08%)	256 (100%)	
Fisher's Exact Test 0.12#				

Table 51: Headache at Day 5 among the patients with respect to treatment group

Figure 51: Headache at Day 5 among the patients with respect to treatment group



	Cough		Total (%)	
Trt. Grps.	No	Yes		
STD	96 (38%)	32 (13%)	128 (50%)	
STDMED	107 (42%)	21 (08%)	128 (50%)	
Total	203 (79%)	53 (21%)	256 (100%)	
Fisher's Exact Test 0.06#				

Table 52: Cough at Day 6 among the patients with respect to treatment group

Figure 52: Cough at Day 6 among the patients with respect to treatment group



	Sore 7	Total (%)		
Trt. Grps.	No	Yes		
STD	126 (49%)	02 (01%)	128 (50%)	
STDMED	125 (49%)	03 (01%)	128 (50%)	
Total	251 (98%)	05 (02%)	256 (100%)	
Fisher's Exact Test 0.5#				

Table 53: Sore Throat at Day 6 among the patients with respect to treatment group

Figure 53: Sore Throat at Day 6 among the patients with respect to treatment group



	Ma	Total (%)		
Trt. Grps.	No	Yes		
STD	126 (49%)	02 (01%)	128 (50%)	
STDMED	122 (48%)	06 (02%)	128 (50%)	
Total	248 (97%)	08 (03%)	256 (100%)	
Fisher's Exact Test 0.14#				

Table 54: Malaise at Day 6 among the patients with respect to treatment group

Figure 54: Malaise at Day 6 among the patients with respect to treatment group



	Dys	Total (%)		
Trt. Grps.	No	Yes		
STD	124 (48%)	04 (02%)	128 (50%)	
STDMED	124 (48%)	04 (02%)	128 (50%)	
Total	248 (97%)	08 (03%)	256 (100%)	
Fisher's Exact Test 0.6#				

	Table 55	5: Dyspnea at	t Day 6	among the patients	with respect to the	reatment group
--	----------	---------------	---------	--------------------	---------------------	----------------

Figure 55: Dyspnea at Day 6 among the patients with respect to treatment group



	Hea		Total (%)	
Trt Crns	No	Vos		
		105		
STD	121 (47%)	07 (03%)	128 (50%)	
STDMED	124 (48%)	04 (02%)	128 (50%)	
Total	245 (96%)	11 (04%)	256 (100%)	
Fisher's Exact Test 0.2#				

Table 56: Headache at Day 6 among the patients with respect to treatment group

Figure 56: Headache at Day 6 among the patients with respect to treatment group



	Cough		Total (%)
Trt. Grps.	No	Yes	
STD	103 (40%)	25 (10%)	128 (50%)
STDMED	110 (43%)	18 (07%)	128 (50%)
Total	213 (83%)	43 (17%)	256 (100%)
Fisher's Exact Test 0.15#			

Table 57: Cough at Day 7 among the patients with respect to treatment group

Figure 57: Cough at Day 7 among the patients with respect to treatment group



Tuble cot porce infour at Day / among the partons with respect to treatment group				
	Sore '	Total (%)		
Trt. Grps.	No	Yes		
STD	126 (49%)	02 (01%)	128 (50%)	
STDMED	125 (49%)	03 (01%)	128 (50%)	
Total	251 (98%)	05 (02%)	256 (100%)	
Fisher's Exact Test 0.5#				

 Table 58: Sore Throat at Day 7 among the patients with respect to treatment group





	Mal	Total (%)		
Trt. Grps.	No	Yes		
STD	126 (49%)	02 (01%)	128 (50%)	
STDMED	125 (49%)	03 (01%)	128 (50%)	
Total	251 (98%)	05 (02%)	256 (100%)	
Fisher's Exact Test 0.5#				

Table 59: Malaise at Day	7 among the	patients with res	pect to treatment group
--------------------------	-------------	-------------------	-------------------------

Figure 59: Malaise at Day 7 among the patients with respect to treatment group



	Dys	Total (%)		
Trt. Grps.	No	Yes		
STD	127 (49.5%)	01 (0.5%))128 (50%)	
STDMED	126 (49%)	02 (01%)	128 (50%)	
Total	253 (99%)	03 (01%)	256 (100%)	
Fisher's Exact Test 0.5#				

Table 60: Dyspnea at Day 7 among the patients with respect to treatment group

Figure 60: Dyspnea at Day 7 among the patients with respect to treatment group



	Head	Total (%)		
Trt. Grps.	No	Yes		
STD	123 (48%)	05 (02%)	128 (50%)	
STDMED	125 (49%)	03 (01%)	128 (50%)	
Total	248 (97%)	08 (03%)	256 (100%)	
Fisher's Exact Test 0.36				

Table 61: Headache at Day 7 among the patients with respect to treatment group

Figure 61: Headache at Day 7 among the patients with respect to treatment group



There was no mortality found in both the treatment groups. Flatulence was observed in 12 patients (9.3%) of Medihope group. This adverse effect was not found in patients in Standard group.

DISCUSSION:

Lantana camara, is one of the most toxic plants with diverse and broad geographic distribution⁸⁻¹². Its toxicity has been reported in animals¹³. The plant extracts of *L. camara* are used in folk medicine for the treatment of catarrhal infections, cancers, ulcers, asthma, high blood pressure, swellings, tetanus, malaria, chicken pox, bronchitis, respiratory diseases, and rheumatism¹⁴⁻¹⁵. Of pharmacological therapeutic importance, *L. camara* methanolic extract was reported to exhibit anti-leishmanial activity against the promastigote forms of *Leishmania amazonensis* ¹⁵. On the other hand, *L. camara* oil is used for the treatment of skin itches, as an antiseptic for wounds, and externally for leprosy and scabies¹⁰. In addition, substantial evidence from the literature indicates that essential oil from the leaves of *L. camara* exhibit anti-inflammatory, antibacterial, antifungal, and antimicrobial activities¹⁶⁻¹⁹.

According to Ayurveda, the wood of *T. grandis* is acrid, cooling, laxative, sedative to gravid uterus and is useful in the treatment of piles, leukoderma and dysentery. Roots are useful in anuria and retention of urine^{20,21}. The flowers are acrid, bitter, dry and cure bronchitis, biliousness, urinary discharges, etc. According to Unani system of medicine, its oil is useful in scabies, whereas the wood is best used for headache, biliousness, burning sensation and pain and liver-related troubles²⁰. It allays thirst, and acts as an anthelmintic, expectorant and anti-inflammatory agent^{20,21}. The bark is astringent, acrid, cooling, constipating, anthelmintic and depurative. It is useful in bronchitis, hyperacidity, vitiated conditions of pitta; dysentery, verminosis, burning sensation, diabetes, leprosy and skin diseases²².

Murraya paniculata L. (*Rutaceae*) locally known as *Orange Jessamine* is a commonly used spice in Pakistan. It is added to food and beverages by local peoples to enhance flavor and fragrance besides its various therapeutic applications. Its leaves are used in preparing soup, fish, meat and chicken dishes. The ground bark of stem is used in various drinks while ground root is also eaten.

The plant is well-known due to its therapeutic efficacy also. The ground bark of stem is used as antidote in snake bites while ground root is used to cure body ache. The leaves are stimulant, astringent and utilized by the local community for relief from diarrhea and dysentery²³⁻²⁵. It is also used to treat cough, hysteria and rheumatism²⁶. It is taken as drink for the treatment of venom bite or as a scrubber on bitted limb. The root and bark is chewed and rubbed to skin to cure body aches. The crushed leaf is applied on fresh cuts, and drunk in dropsy as remedy. It can be used in treatment of toothache, stomachache and gout. It has abortive function and used in treatment of venereal disease²⁷⁻²⁹.

Various biological activities of *Murraya paniculata* have been proved like analgesic³⁰, anti-giardial³¹, anti-amoebic³², antidiarrhoeal, anti-inflammatory, larvicidal, antioxidant, anti-implantation, anti-diabetic, antinociceptive, oxytocic and antifungal activities³³.

Terminalia paniculata (*T. paniculata*) Roth (Combretaceae) is a large deciduous tree distributed in western and eastern Ghats, in the semi-evergreen and moist deciduous forests of India. The bark is astringent, bitter, cooling and useful in vitiated conditions of kapha and pitta, cough, bronchitis, strangury, diabetes, skin diseases, leprosy condition³⁴. The hepatoprotective and anti-inflammatory activity of its bark was reported^{35, 36}.

Toddalia asiatica var. gracilis (L) Lam., (Family –Rutaceae) known as "Milakarani" in Tamil, 'Kanchana' in Sanskrit, 'Kanj' in Hindi, is commonly used in Indian systems of medicine like Ayurveda and siddha for malaria, rheumatism and fever^{37,38}. Fruits are eaten for relief form burning sensation in stomach³⁹. Leaf and root is used to cure rheumatic swellings, fever pain in the bowles. This therapeutic value is due to the presence of coumarins⁴⁰.

Toddalia is a monotypic genus consisting of species *Toddalia asiatica* (Linn.) Lam. (Rutaceae), wellknown as Lopez root or Wild orange tree. In Indian systems of medicine such as Ayurveda and Siddha, it is commonly used for treatment of malaria, rheumatism and fever. Also used for the treatment of cough, indigestion, lung diseases, stomach ailments, cholera, and diarrhea^{41,42}.

Several chemical constituents with varied chemical nature like benzophenanthridine, quinoline, and protoberberine alkaloids, coumarins, terpenoids, cyclohexylamines and others were isolated from this plant. The plant has been reported to possess pharmacological activities such as anticancer, antimalarial, anti-HIV activities, antiplatelet aggregation, antipyretic, anti-inflammatory, analgesic, wound healing and antimicrobial activities⁴³. Benzophenanthridine alkaloid, nitidine possess anti-HIV, antimalarial activity^{44, 45}. Dihydronitidne isolated from stem chips exhibited cytotoxic activity toward human lung carcinoma⁴⁶.

Nothapodytes foetida (also known as Mappia foetida or Nothapodytes nimmoniana) is a medium size tree belonging to family Icacinaceae. It is distributed in Southern India, North India, Srilanka, Myanmar and Thailand⁴⁷. 9-methoxy camptothecin is also characterized from Nothapodytes foetida⁴⁸ which showed anticancer activity⁴⁹.

Nothapodytes nimmoniana (Grah.) Mabb., (Icacinaceae), (Syn.: *Nothapodytes foetida, Mappia foetida*) is one such plant. It is a rich source of potent alkaloid camptothecin (CPT) and 9-methoxycamptothecin⁵⁰⁻⁵². The metabolites extracted from *N. nimmoniana* show anti *human immunodeficiency virus*, anti-neoplastic, and anti-malarial activity⁵⁰.

In the present study, 89 patients (34.6%) were recruited from Swargiya Shrimati Sindhutai Vikhe Patil, Covid Care Center, Ahmednagar, while 167 patients (65.2%) were recruited from Dedicated Covid Hospital, Loni. Of the 256 patients, majority of patients were Males (162, 63.3%) as compared to Females (36.7%).

With respect to comorbidities, 50 patients (19.5%) reported history of hypertension, while 37 patients (14.5%) reported history of diabetes. The patients were equally distributed (128 each) in both 'Standard' and 'Standard + Medihope group'.

There was no statistically significant difference observed in treatment groups with respect to gender (Table 11). Thus, the groups were comparable with respect to gender.

On intra group comparison of the WBC count and Lymphocyte count was significantly raised in both Standard and Medihope group. However, the increase in the WBC count was higher in Standard group (-1162.32±2939.71) as compared to Medihope group (-733.60±2520.05). Higher TLC levels are associated with severe COVID-19⁵³. Thus there was lesser increase in the WBC in Mediphope group, indicating a better prognosis, although statistically nonsignificant.

On comparing the mean temperature on Day 1 and Day 7 between the treatment groups, there was statistically significant reduction in both groups (Table 22). There was a decreasing trend in the temperature in both treatment groups, but there was rapid fill in temperature on second day of treatment in Medihope group as compared to Standard group. However, on comparing the difference between the baseline and Day 7 values of Standard group vs Medihope group, the temperature difference in the Medihope group was larger, however, it was statistically insignificant (Table 18). Thus, there was earlier fall in temperature in Medihope group.

On comparing the mean Spo2 levels on Day 1 and Day 7 between the treatment groups, there was statistically significant increase in both groups (Table 23). There was an increasing trend in the Spo2 levels in both treatment groups, but the mean Spo2 levels of Medihope group were consistently higher when compared to Standard group. However, on comparing the difference between the baseline and Day 7 values of Standard group vs Medihope group, there was no statistically significant difference

found (Table 19). Thus, there was higher rise in Spo2 levels in Medihope group when compared to Standard group.

On comparing the mean Respiratory rate on Day 1 and Day 7 between the treatment groups, there was statistically significant reduction in both groups (Table 24). There was a decreasing trend in the Respiratory rate in both treatment groups, but the mean RR was consistently lower in the Medihope group when compared with Standard group. However, on comparing the difference between the baseline and Day 7 values of Standard group vs Medihope group, there was no statistically significant difference found (Table 20). Thus there was earlier fall in Respiratory rate in the Medihope group.

There was no difference observed in the mean stay in hospital between the treatment groups. All patients in the study, irrespective of the treatment allotted, showed improvement in X-ray chest finding with respect to reduction in haziness of the chest fields. Patients with normal report showed no change in the report after treatment. Thus comparable outcomes were found among the groups in terms of days of hospital stay and changes in Chest X ray

The number of patients with complaint of Cough was greater in the Medihope group. There number of patient with cough in both groups were equal in both treatment groups on 5th day, while the number was further lower in Medihope group on 6th and 7 day of treatment.

The number of patients with complaint of Sore throat was greater in the Medihope group. There was steep decline in the number of patient with Sore throat in Medihope group on Day 2 and 3, while the number on day 4 was lower in Standard group and the numbers were equal in both treatment groups on Day 5, Day 6 and Day 7.

The number of patients with complaints of Malaise and Dyspnea on Day 1 were higher in Medihope group as compared to Standard group. There was steep decline in the number of patient with Malaise from Day 2, while the decline was observed on Day 3 in Standard group.

The number of patients with complaint of Dyspnea was greater in the Medihope group. There was steep decline in the number of patient with Dyspnea from Day 2, while there was an increase in Standard group on day 2 followed by fall in number on subsequent days.

The number of patients with complaint of Headache was greater in the Medihope group. There was steep decline in the number of patient with Headache from Day 2, while there was an increase in Standard group on day 2 followed by fall in number on subsequent days. The number of patients was consistently lower in the Medihope group as compared to Standard group.

The above results of comparison of various symptoms of disease among the treatment groups indicate earlier relief from symptoms among the patients of Medihope group as compared to the Standard group.

There was no mortality found in both the treatment groups. Flatulence was observed in 12 patients (9.3%) of Medihope group. This adverse effect was not found in patients in Standard group.

CONCLUSION:

The groups were comparable with respect to gender and age. Thus there was lesser increase in the WBC in Mediphope group, indicating a better prognosis, although statistically nonsignificant. There was earlier fall in temperature and Respiratory rate, higher rise in Spo2 levels in patients of Medihope group as compared to that of the Standard group. There was earlier relief from symptoms among the patients of Medihope group as compared to the Standard group.

The outcomes were related to mean duration of hospital stay and changes in Chest X ray were comparable among the groups. There was no mortality found in both the treatment groups. Flatulence was observed in 12 patients (9.3%) of Medihope group.

Thus, Medihope may be advocated in patients with mild and moderate severity patients of Corona infection along with Standard treatment as add on therapy for earlier mitigation of deranged temperature, Respiratory rate, WBC count, Spo2 levels and symptoms.

REFERENCES

- Sharma Ram Karan, Dash Vaidya Bhagwan, editors. Charaka Samhita of Agnivesha, text with English translation of Ayurveda Dipika commentary of Chakrapanidatta. Varanasi: Chowkhambha Sanskrit Series; 2003. Reprint.
- Central Council for Research in Ayurveda and Siddha. Management of Chikungunya through Ayurveda and Siddha. New Delhi. 2009. http://www.ccras. nic.in/sites/default/files/22092016_MANAGEMENT%200F%20CHIKUNGUNYA %20TH ROUGH%20AYURVEDA%20AND%20SIDDHA-A%20TECHNICAL% 20REPORT.pdf)
- 3. Bhandari etal. Clinico-Radiological Evaluation and Correlation of CT Chest Images with Progress of Disease in COVID-19 Patients. J Assoc Physicians India. 2020 Jul;68(7):34-42.
- 4. Standard treatment protocol for COVID 19 Revision 4 by FDA Dated-22.07.2020
- 5. AYUSH guideline for conduct of clinical trials on Ayurvedic medications.
- 6. ICMR guideline for conduct of clinical trials on Ayurvedic medications.
- 7. ICHGCP 6 guidelines.
- 8. Sharma O.P., Makkar H.P., Dawra R.K. A review of the noxious plant *Lantana camara*. *Toxicon*. 1988;26:975–987. doi: 10.1016/0041-0101(88)90196-1.
- Ghisalberti E.L. Lantana camara Linn (Review) Fitoterapia. 2000;71:467–485. doi: 10.1016/S0367-326X(00)00202-1.
- Day M.D., Wiley C.J., Playford J., Zalucki M.P. Lantana: Current Management Status and Future Prospects. Australian Centre for International Agricultural Research; Canberra, Australia: 2003.
- 11. Kalita S., Kumar G., Karthik L., Rao K.V.B. A review on medicinal properties of *Lantana camara*. *Res. J. Pharm. Technol.* 2012;5:771–775.

- 12. Bhagwat S.A., Breman E., Thekaekara T., Thornton T.F., Willis K.J. A battle lost? Report on two centuries of invasion and management of *Lantana camara* L. in Australia, India and South Africa. *PLoS ONE*. 2012;7:e32407. doi: 10.1371/journal.pone.0032407.
- 13. Sharma O.P., Makkar H.P., Dawra R.K., Negi S.S. A review of the toxicity of *Lantana camara* (Linn) in animals. *Clin. Toxicol.* 1981;18:1077–1094. doi: 10.3109/15563658108990337.
- 14. Tripathi A.K., Shukla B.N. Antifungal activity of some plant extracts against *Fusarium oxysporum* sp. causing wilt of linseed. J. Mycol. Plant Pathol. 2002;32:266–267.
- 15. Braga F.G., Bouzada M.L.M., Fabri R.L., Matos M.O., Moreira F.O., Scio E., Coimbra E.S. Antileishmanial and antifungal activity of plants used in traditional medicine in Brazil. J. *Ethnopharmacol.* 2007;111:396–402. doi: 10.1016/j.jep.2006.12.006.
- 16. Deena M.J., Thoppil J.E. Antimicrobial activity of the essential oil of *Lantana camara*. *Fitoterapia*. 2000;71:453–455. doi: 10.1016/S0367-326X(00)00140-4.
- 17. Begum S., Wahab A., Siddiqui B.S. Pentacyclic tri-terpenoids from the aerial parts of *Lantana camara*. *Chem. Pharm. Bull*. 2003;51:134–137. doi: 10.1248/cpb.51.134.
- Kumar V.P., Chauhan N.S., Padh H., Rajani M. Search for antibacterial and antifungal agents from selected Indian medicinal plants. *J. Ethnopharmacol.* 2006;107:182–188. doi: 10.1016/j.jep.2006.03.013.
- Seth R., Mohan M., Singh P., Haider S.Z., Gupta S., Bajpai I., Singh D., Dobhal R. Chemical composition and antibacterial properties of the essential oil and extracts of *Lantana camara* Linn. from Uttarakhand (India) *Asian Pac. J. Trop. Biomed.* 2012;2:S1407–S1411. doi: 10.1016/S2221-1691(12)60426-2.

- 20. Oudhia P. Medicinal herbs of Chhattisgarh, India, having less known traditional uses. I. Sagon Tectona grandis, family Verbanaceae. Available from: <u>http://www.Botanical.com</u>[©] [Last cited on 5th February 2021]
- Sharma PV. *Text book of Dravya- guna*. Varanasi: Chaukhambha Bharti Prakashan; 1986.
 Shaka Riktniryas Chaukhambha Bharti Academy; pp. 791–3.
- 22. Ghaisas M, Navghare V, Takawale A, Zope V, Tanwar M, Deshpande A. Effect of Tectona grandis Linn. On dexamethasone-induced insulin resistance in mice. J *Ethnopharmacol.* 2009;122:304–7.
- Parrotta JA. Healing plants of Peninsular India. Wallingford, UK and New York: CABI Publishing; 2001. p. 917.
- Kiritikar KR, Basu BD. Indian Medicinal Plants. 2nd ed. Dehredun, India:Mahendra Pal Sing Publication; 1987.
- 25. Bhattacharjee SK. Hand book of medicinal plants. 2001, 3: 231.
- Ghani A. Medicinal Plants of Bangladesh: Chemical constituents and Uses.Dhaka. Asia Soc Bang. 2003;2:309–10.
- 27. Kinoshita T, Firman K. Highly oxygenated flavonoids from Murraya paniculata. Phytochem. 1996;42:1207–10.
- 28. Rahman AU, Shabbir M, Sultani SZ, Jabbar A, Choudhary MI. Cinnamates and coumarins from the leaves of Murraya paniculata. Phytochem.
- 8. 1997;44:683–5.
- 29. Rahman A, Uddin HN, Shahid IZ. Antidiarrhoeal and anti-inflammatory activities of Murraya paniculata (L.) jack. Pharmacologyonline. 2010;3:768–76.
- Podder MN, Das BN, Saha A, Ahmed M. Analgesic activity of bark of Murraya paniculata. Int J Med Medical Sci. 2011;3:105–8.

- 31. Sawangjaroen N, Subhadhirasakul S, Phongpaichit S, Siripanth C, Jamjaroen K, Sawangjaroen K. The in vitro anti-giardial activity of extracts from plants that are used for self-medication by AIDS patients in southern Thailand. Parasitol Res. 2005;95:17–21.
- 32. Sawangjaroen N, Phongpaichit S, Subhadhirasakul S, Visutthi M, Srisuwan N, Thammapalerd N. The anti-amoebic activity of some medicinal plants used by AIDS patients in southern Thailand. Parasitol Res. 2006;98:588–92.
- Kosai P, Jiraungkoorskul W. Review of hypoglycemic activity of Murraya paniculata Linn. Adv Environment Bio. 2015;9:466–72.
- Varier PS. Indian medicinal plants compendium of 500 species. Hyderabad: Orient Longman Ltd; 1995.
- 35. Eesha BR, Mohanbabu AV, Meena KK, et al. Hepatoprotective activity of *Terminalia paniculata* against paracetamol induced hepatocellular damage in Wistar albino rats. *Asian Pacific Journal of Tropical Medicine*. 2011;4(6):466–469.
- 36. Talwar S, Nandakumar K, Nayak PG, et al. Anti-inflammatory activity of *Terminalia paniculata* bark extract against acute and chronic inflammation in rats. *Journal of Ethnopharmacology*. 2011;134(2):323–328

- 37. Kirtikar, K.R. and Basu, B.D., Indian Medicinal plants, Lalit Mohan Basu, MB allahabad, India, Vol 465-467, (1933)
- Chopra, R.N., Nayer, S.L. and Chopra, I.C., Glossary of Indian Medical Plants. Ist Edn., CSIR, New Delhi, 245, (1956)
- Ramachandran, V.S. and Nair, V.C., Ethnobotanical observations on Irulars of Tamil Nadu (India) J.Econ. Tax Bot, 2: 183-190, (1981)
- 40. Bandara, B.M.R., Hewage., C.M., Jayamanne, D.H.L.W and Karunaratne V., Biological activity of some steam distillates from leaves of ten species of Rutaceous plants, J. Natn Sci Coun. Srilanka, 18(1): 71-77, (1990).
- 41. Kirtikar KR, Basu BD. International Book Distributor. I. India: Dehradun; 1987. Indian medicinal Plants; pp. 465–7.
- 42. Chopra RN, Nayer SL, Chopra IC. Ist ed. New Delhi: CSIR; 1956. (1956) Glossary of Indian Medical Plants; p. 245.
- 43. Molmoori RK, Rodda HC, Asres K, Veeresham C. *Toddalia asiatica* (Linn) Lam-A comprehensive review. *Pharmacogn Rev.* 2008;2:386–97.
- 44. Rashid MA, Gustafson KR, Kashman Y, Cardellina JH, II, McMahon JB, Boyd MR. Anti-HIV alkaloids from *T. asiatica*. *Nat Prod Lett*. 1995;6:153–6.
- 45. Gakunju DM, Mberu EK, Dossaji SF, Gray AI, Waigh RD, Waterman PG, et al. Potent antimalarial activity of the alkaloid nitidine, isolated from a Kenyan herbal remedy. *Antimicrob Agents Chemother*. 1995;39:2606–9.
- 46. Iwasaki H, Oku H, Takara R, Miyahira H, Hanashiro K, Yoshida Y, et al. The tumor specific cytotoxicity of dihydronitidine from *Toddalia asiatica* Lam. *Cancer Chemother Pharmacol.* 2006;58:451–9.

- 47. H. C. Gowda, R. Vasudeva, P. G. Mathachen, R. Umashanker, R. Shaanker and K. N Ganeshaiah. Breeding types in Nothapodytes nimmoniana Graham. Curr. Sci. 83: 1077–78 (2002).
- 48. Hsiao HY, Cheng TJ, Yang GM, Huang IJ, Chen RL. Determination of camptothecins in DMSO extracts of Nothapodytes foetida by direct injection capillary electrophoresis. Phytochem Anal 2008;19:136-40.
- 49. 10. Liao N, Zhang P, Ao M, Wang J, Shi Y, Yu L, et al 9-methoxycamptothecin from Nothapodytes foetida induces apoptosis in murine sarcoma S180 cells. Z Naturforsch C 2011;66:471-6.
- 50. Govindachari TR, Viswanathan N. Alkaloids of *Mappia foetida*. *Phytochemistry*. 1972;11:3529–31.
- 51. Fulzele DP, Satdive RK, Pol BB. Growth and production of camptothecin by cell suspension cultures of *Nothapodytes foetida*. *Planta Med*. 2001;67:150–2.
- 52. Pai SR, Nimbalkar MS, Pawar NV, Patil RP, Dixit GB. Seasonal discrepancy in phenolic content and antioxidant properties from bark of *Nothapodytes nimmoniana* (Grah.) Mabb. *Int J Pharm Biol Sci.* 2010;1:1–17.
- 53. Anurag A, Jha PK, Kumar A. Differential white blood cell count in the COVID-19: A crosssectional study of 148 patients. Diabetes Metab Syndr. 2020;14(6):2099-2102.

Clinical Study Report

CLINICAL STUDY REPORT SIGNATURE PAGE Utility of Medihope as an addon therapy for Covid 19 patients: An Open labeled, Non-Randomized, Multicentric, Phase III Clinical. CTRI number: CTRI2020/09/027975 registered on 22/09/2020

	SIGNATURE:	DATE:
PRINCIPAL INVESTIGATORS		
Dr. Mahajan, Professor & Head, Medicine, RMC, Loni.	Chap your	2412/21
Dr. Rahul Kunkulol, Professor & Head, Pharmacology, RMC, Loni	Falsant	2002 21
Dr. Sandeep Narwane, Associate Professor, Pharmacology, RMC, Loni.	Bar	24/02/21
BIOSTATISTICIAN		
Dr. Anup Kharde, Associate Professor, Community Medicine, RMC, Loni.	GANYPIC	24/02/21
PREPARED BY		
Dr. Sandeep Narwane, Associate Professor, Pharmacology, RMC, Loni.	\$2	24/02/21

Conclusion of study:

The groups were comparable with respect to gender and age. Thus there was lesser increase in the WBC in Mediphope group, indicating a better prognosis, although statistically nonsignificant. There was earlier fall in temperature and Respiratory rate, higher rise in Spo2 levels in patients of Medihope group as compared to that of the Standard group. There was earlier relief from symptoms among the patients of Medihope group as compared to the Standard group.

The outcomes were related to mean duration of hospital stay and changes in Chest X ray were comparable among the groups.

Medihope may be advocated in patients with mild and moderate severity patients of Corona infection along with Standard treatment as add on therapy for earlier mitigation of deranged temperature, Respiratory rate, WBC count, Spo2 levels and symptoms.

Kindly find attached complete project report.

Handed over to "Hope" Ayurvedic Medicine Pvt. Ltd.

Confidential (This document contains confidential and proprietary information. Do not copy or distribute without written permission)