Clinical Trial Details (PDF Generation Date :- Sat, 30 Sep 2023 10:19:56 GMT)

CTRI Number	CTRI/2020/07/026841 [Registered on: 28/07/2020] - **Trial Registered Prospectively**
Last Modified On	27/07/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug Ayurveda
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	A clinical trial to study the effects of an Ayurvedic medicine, Haldi 30 (Turmeric extract) drops in patients with Corona virus infection.
Scientific Title of Study	Efficacy of Ayurvedic Medicine Haldi 30 drops as an Add on medication to standard of care in adult patients of mild to moderate COVID 19. A Phase II randomized, single - blind, parallel group, placebo - controlled trial.

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Sarang Phadke
Designation	Ayurvedic Physician
Affiliation	Sahyadri Hospitals Limited
Address	Sahyadri Hospitals Limited Plot no 9 B, Neeta Society, S No 1484 / B, Paud Road, Kothrud, Pune MAHARASHTRA 411038 India
Phone	9561071607
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Sarang Phadke
Designation	Ayurvedic Physician
Affiliation	Sahyadri Hospitals Limited
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Source of Monetary or Material Support

Source of Monetary or Material Support
> Sahyadri Hospitals Limited Plot no 9 B, Neeta Society, S No 1484 / B, Paud Road, Kothrud,Pune, Maharashtra, India

Primary Sponsor

Primary Sponsor Details	
Name	Dr Sarang Phadke
Address	8 , Vinayak Apartments , 8 , Gananjay Society Unit no2 , Kothrud, Pune 411038 MAHARASHTRA India
Type of Sponsor	Other [Self]

Details of Secondary Sponsor

Name	Address
Col Suresh Purushottam Gadgil	ShriKripa, Plot no 26, Lokmanya housing society, Pandharpur road, Miraj, Sangli 416410
Mr Anant Krishnaji Joshi	Plot no 17 B, Chandragupta co operative housing society, Poud road, Kothrud, Pune 411038
Mr Narahar Krishna Phadke	8 , Vinayak Apartments , 8 , Gananjay Society Unit no2 , Kothrud , Pune , Maharashtra , 411038 , India
Mr Nikhil Vishwas Ranade	Srushti, Plot no 36, Swaroop colony, Anandnagar, Sinhagad road, Pune 411051
Mr Sunil Danekar	A 601, Shreemanyogi, Shivraj Nagar, Rahatani, Pune 411017
Mr Vishwas Digambar Ranade	Srushti, Plot no 36, Swaroop colony, Anandnagar, Sinhagad road, Pune 411051
Sanmarga Pratishthan	8 , Vinayak Apartments , 8 , Gananjay Society Unit no2 , Kothrud , Pune , Maharashtra , 411038 , India

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Sarang Phadke	Sahyadri Hospital, Kothrud branch 2	Branch 2 of Sahyadri Hospitals Limited , PMC listed COVID 19 dedicated hospital (All wards and all rooms), Plot no 9 B, Neena Society, S No 1484A and B, Paud Road, Kothrud, Pune 411038 Pune MAHARASHTRA	9561071607 nmission21@yahoo.co.in
Dr Sarang Phadke	Sahyadri Superspeciality Hospital, Deccan Gymkhana branch 1	Branch 1 of Sahyadri Hospitals Limited,COVID 19 Isolation wards, 6th and 8th floor, Plot no 30 C, Erandwane, Deccan Gymkhana, Pune Pune MAHARASHTRA	9561071607 nmission21@yahoo.co.in

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Sahyadri Hospitals Ltd Ethics Committee	Approved	08/07/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Coronavirus as the cause of diseases classified elsewhere

Intervention / Comparator Agent

Type	Name	Details
Intervention	Standard of care plus Haldi 30 drops	Standard of care plus 3 drops PO at 6 AM, 10 AM, 2 PM, 6 PM, 10 PM. No liquid or solid food or oral medication up to 20 minutes after drug administration.
Comparator Agent	Standard of care plus Sesame oil drops	Standard of care plus 3 drops PO at 6 AM, 10 AM, 2 PM, 6 PM, 10 PM. No liquid or solid food or oral medication up to 20 minutes after drug administration.

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	COVID 19 positive patients 1 Mild category Group A Asymptomatic but positive for COVID 19. Group B Symptomatic URTI without comorbidity. Group C Symptomatic URTI with comorbidity. 2 Moderate category Pneumonia hypoxia , fever , cough including SpO2 less than 94 percent Range 90 to 94 percent on room air. Respiratory Rate more or equal to 24 per minute. 3. Male or non-pregnant female of Age ? 18 years at time of consent. 4. Women of child bearing potential agree to abstinence or one primary form of non-hormonal contraception during the study period. 5. Subject / LAR willing to give informed consent for the study and agrees not to participate in another clinical trial for COVID-19 during the course of this study and further agrees to be randomized to any treatment arm of the study.

Exclusion Criteria

Exclusion Criteria	
Details	COVID 19 positive patients 1 Stage II B Group E Pneumonia LRTI with respiratory failure. 2 Stage III Group F Pneumonia LRTI with respiratory failure multi organ dysfunction syndrome. 3 Physician makes the decision that trial is not in the best interest of the patient. 4 Anticipated discharge to another hospital within 72 hours. 5 Subject already on another trial for COVID-19

Method of Generating Random Sequence	Coin toss, Lottery, toss of dice, shuffling cards etc
Method of Concealment	Pre-numbered or coded identical Containers
Blinding/Masking	Participant Blinded

Primary Outcome

Outcome	Timepoints
Time to Recovery	Time to Recovery as defined on the Ordinal Scale censured at day 7

Secondary Outcome

Outcome	Timepoints
1 Change from baseline in monitored laboratory values 2 Change from baseline in Ordinal scale assessment 3 Mortality at day 7 4 Duration of hospitalization, use of NIV/HFNO 5 Incidence of new use of IMV/ECMO	Day 3, Day 5 ,Day 7

Target Sample Size	**Total Sample Size=**260 **Sample Size from India=**260 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	Phase 2
Date of First Enrollment (India)	03/08/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**3 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	None yet.
Brief Summary	This study is a phase II, randomized, single blind, parallel group, placebo controlled to assess the efficacy of Haldi 30 drops (*Curcuma Longa* extract) 3 drops 5 times daily for 7 days as an add on medication to the standard of care treatment in adult patients of mild to moderate COVID 19 Infection that will be conducted in two branches of Sahyadri Hospitals Limited at Pune, Maharashtra in India. The primary outcome measure will be time to recovery as defined on the eight category ordinal scale censured at day 7. The secondary outcome measures will be 1. Change from baseline in monitored laboratory values of RT PCR, IL 6 level, Ferritin level, Haemogram, D Dimer and X Ray Chest, 2. Change from baseline in the eight category ordinal scale assessment, 3. Incidence of use of Oxygen support.