Clinical Trial Details (PDF Generation Date :- Fri, 16 Apr 2021 20:34:15 GMT)

CTRI Number	CTRI/2020/09/027914 [Registered on: 19/09/2020] - **Trial Registered Prospectively**
Last Modified On	13/04/2021
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Ayurveda
Study Design	Randomized, Parallel Group Trial
Public Title of Study	Evaluation of efficacy of Fixed Ayurvedic Regimen of Giloy Ki Ghan Vati,Tulsi Tablets,Kalmegh Tablets and Dabur Chyawanprash in COVID-19
Scientific Title of Study	A Prospective, Randomized, Open Label Blinded End Point (PROBE) Two arm Comparative Clinical Study to Evaluate the Efficacy and Safety of Fixed Ayurvedic Regimen (Giloy Ki Ghan Vati, Tulsi Tablets, Kalmegh Tablets and Dabur Chyawanprash) as an Add on to Conventional Treatment in the management of Mild and Moderate COVID-19 Patients

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

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

Details of Principal Investigator	
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Source of Monetary or Material Support

Source of Monetary or Material Support
> Dabur India Limited Plot No.22 Site IV Sahibabad (Ghaziabad) UP 201010

Primary Sponsor

Primary Sponsor Details	
Name	Dabur India Limited
Address	Plot No.22 Site IV Sahibabad (Ghaziabad) UP 201010
Type of Sponsor	Other [Ayurvedic Healthcare]

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Narendra B Mundhe	KVTR Ayurveda College, Boradi	Department of Kayachikitsa Room No.5 Dhule MAHARASHTRA	9850378206 912262363654 drnbmundhe@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Karamvir V.T. Randhir Ayurved College, Boradi	Approved	11/09/2020	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	Tulsi tablets	1 Tablet two times a day for 28 days
Intervention	Giloy ki Ghanvati	1 Tablet two times a day for 28 days
Intervention	Kalmegh Tablets	1 Tablet two times a day for 28 days
Intervention	Dabur chyawanprash	1 Teaspoonful (Approx 10-12 grams) two times a day for 28 days
Comparator Agent	Standard care	Conventional Treatment as advised / prescribed by concerned health authorities

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	60.00 Year(s)
Gender	Both
Details	1. Male and female subjects between the age groups of 18 and 60 years 2. Clinical presentation with Laboratory (RT-PCR or

	Rapid antigen or any other test for COVID19 as per current guidelines) confirmed infection of COVID-19 3. Subjects having symptoms not more than 3 days 4. Patients with mild to moderate symptoms [as per US-CDC classification of COVID-19 (Ref: www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidancemanagement-patients.html) (Mild symptoms up to mild pneumonia) 5. Ready to provide written informed consent for participation in the study 6. Willing to follow COVID-19 (prevention and containment) related guidelines issued from time to time by Govt./ local health authority throughout the study period.

Exclusion Criteria

Exclusion Criteria	
Details	1. Patients suffering from severe COVID-19 disease as judged by a physician and fulfilling at least two of the following three criteria (i) Respiratory distress at room ambience (?30 breaths per min) (ii) Oxygen saturation at rest ?93% (peripheral digital oximeter) and requiring oxygen support for over one hour to normalize (iii) Any of the known COVID-19 complications and emergency procedures which may require shift/admission in intensive care unit such as respiratory failure, adult respiratory distress syndrome, requirement of oxygen support for over 1 hour, requirement of mechanical ventilation, septic shock, or severe non-respiratory organ dysfunction or failure. 2.Patients with known history of Diabetes Mellitus 3.Patients having difficulty in swallowing oral medications. 4.AYUSH system-based contraindications 5.Patients who have participated in other clinical trials within last 1 month; 6. Chronic, Severe, Unstable, Uncontrolled co-existent medical illness such as, Hypertension, Cardiac disorders, liver, kidney disorders and lung disorders or other disease of concern which may put the patient at increased risk during the study 7. Being pregnant or breastfeeding, or having a positive pregnancy test at the time of pre-dose inspection, or planning to become pregnant within 3 months of study treatment. 8.Subjects having any medical or surgical condition that would require immediate medical or surgical intervention at the time of screening 9.Subjects having immune compromised status like HIV, Hepatitis, Tuberculosis and Cancer etc. 10.Subjects taking steroid treatment and or any kind of immunosuppressive therapy prior to participation in the study 11. Allergies, known to be allergic to Investigational Products (Ayurvedic Formulations) 12. Other conditions, which in the opinion of the investigators, makes the patient unsuitable for enrolment or could interfere with his participation in, and completion of the protocol

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Centralized
Blinding/Masking	Outcome Assessor Blinded

Primary Outcome

Outcome	Timepoints
1. Mean time (days) required for clinical recovery from COVID19 (Day of randomization to the day of clinical recovery and from the day of first noticed symptoms) (Criteria for clinical recovery as mentioned below)	Baseline /Screening, Evaluation during hospitalization, At Discharge Visit, Post Discharge at 14 and 28 day

	2. Proportion of patients showing clinical recovery between the two groups

Secondary Outcome

Outcome	Timepoints
1. Mean time (days) for testing negative for SARS-CoV-2 from the day of randomization and from the day of first noticed symptoms. 2. Assessment of/on-Fever & respiratory symptoms,WHO Ordinal scale,Requirement of Oxygen, ICU admission,Ventilator Support No.of days of hospitalization,% mortality,Post-clinical recovery, Changes in lab safety parameters,chest X–ray,Rescue medication,WHO QOL BRIEF,Global assessment,AE/SAE	Baseline /Screening, Evaluation during hospitalization, At Discharge Visit, Post Discharge at 14 and 28 day

Target Sample Size	**Total Sample Size=**72 **Sample Size from India=**72 **Final Enrollment numbers achieved (Total)=**68 **Final Enrollment numbers achieved (India)=**68
Phase of Trial	Phase 2/ Phase 3
Date of First Enrollment (India)	22/09/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**0 **Days=**28
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	Nil
Brief Summary	COVID 19 is a global pandemic caused by the novel coronavirus SARS-CoV-2. Currently, there is no approved treatment for COVID 19.Ayurveda mentions formulations & herbs like Chyawanprash, Tulsi, Giloy & Kalmegh that are attributed with immunity boosting, antiviral, antiinflammatory & antioxidant properties.Basis the preclinical and clinical study data available on Chyawanprash and abundant published literature on immunomodulator, antiviral, antiinflammatory & antioxidant properties of Tulsi, Giloy and Kalmegh, it may be favorable to consider these for the management of COVID-19. The current study will be a prospective, randomized, open label, blinded end point (PROBE), two arm, comparative clinical study to evaluate the efficacy and safety of a Fixed Ayurvedic Regimen (Giloy Ki Ghan Vati + Tulsi Tablets + Kalmegh Tablets + Dabur Chyawanprash) as an add on to Conventional treatment in the management of Mild & Moderate COVID-19 patients. Primary outcomes assessed will be Mean time (days) required for clinical recovery from COVID19 (Day of randomization to the day of clinical recovery and from the day of first noticed symptoms) & Proportion of patients showing clinical recovery between the two groups. Secondary assessed will be mean time (days) for testing negative for SARS-CoV-2 from the day of randomization and from the day of first noticed symptoms, assessment of fever & respiratory symptoms, WHO Ordinal scale, Requirement of Oxygen, ICU admission, Ventilator Support, No. of days of hospitalization, % mortality, Post-clinical recovery, Changes in lab safety parameters & chest X – ray, Rescue medication, WHO QOL BRIEF, Global assessment, AE/SAE. Assessment will be done at Baseline, During hospitalization, At Discharge Visit, Post Discharge at 14 and 28 day. Patients consuming FAR as add on SOC showed faster and earlier clinical recovery from the day of onset of symptoms by 51.34% (*p<0.05*) as compared to SOC group. A higher proportion of patients taking FAR recovered within the first 2 weeks compared to those taking only SOC. It was observed that 5 times more

patients recovered within 7 days in FAR group when compared to SOC (*p<0.05*) group. An earlier clinical recovery was observed in clinical symptoms like sore throat, cough, loss of taste and myalgia etc. (*p<0.05*). Improvement in post clinical symptoms like appetite, digestion, stress and anxiety was also observed to be better with the use of FAR. Requirement of rescue medications like antipyretics, analgesics and antibiotics was also found to be reduced in FAR group (p<0.05). FAR showed a significant improvement in all the assessed domains of Quality of Life. None of the AEs/SAE reported in the study were assessed to be related to study drugs. Further, FAR did not produce any significant change in the lab safety parameters and was assessed to be safe. Results concluded FAR could be an effective and safe add on Ayurvedic regimen to standard of care in the management of mild & moderate COVID-19 patients.