Clinical Trial Details (PDF Generation Date :- Sat, 30 Sep 2023 12:00:25 GMT)

CTRI Number	CTRI/2020/05/025488 [Registered on: 31/05/2020] - **Trial Registered Prospectively**
Last Modified On	28/05/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Ayurveda
Study Design	Randomized, Parallel Group Trial
Public Title of Study	Clinical study on Guduchi Ghana Vati as a preventive remedy in pandemic of COVID-19
Scientific Title of Study	An Open label, Multi centric, Randomized, Comparative, Prospective, Interventional Community based Clinical Study to Evaluate Safety and Efficacy of Guduchi Ghana Vati as a Preventive Remedy on Healthy Individuals in Pandemic of COVID-19

Secondary IDs if Any

Secondary ID	Identifier
NIA-CVD-19/2020/01 Version 1.0 Dated 20th May 2020	Protocol Number

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

Details of Principal Investigator	
Name	Prof Dr Sanjeev Sharma
Designation	Director
Affiliation	National Institute of Ayurveda, Jaipur
Address	National Institute of Ayurveda, Madhav Vilas Palace, Jorawar Singh Gate, Amer Road, JAIPUR - 302002 (RAJASTHAN) INDIA Jaipur RAJASTHAN 302002 India
Phone	09418079691
Fax	
Email	profsanjeevhp@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr PawanKumar Godatwar
Designation	Associate Professor
Affiliation	National Institute of Ayurveda, Jaipur
Address	Department of Roganidana and Vikriti Vijnana, OPD No. 5, Ground Floor, Madhav Vilas Palace Jorawar Singh Gate Amer Road Jaipur Rajasthan Jaipur, RAJASTHAN Jaipur RAJASTHAN 302002 India
Phone	9314502834
Fax	
Email	gpawankumar@rediffmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr PawanKumar Godatwar
Designation	Associate Professor
Affiliation	National Institute of Ayurveda, Jaipur
Address	Department of Roganidana and Vikriti Vijnana, OPD No. 5, Ground Floor, Madhav Vilas Palace Jorawar Singh Gate Amer Road Jaipur Rajasthan Jaipur, RAJASTHAN Jaipur RAJASTHAN

	302002 India
Phone	9314502834
Fax	
Email	gpawankumar@rediffmail.com

Source of Monetary or Material Support

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> National Institute of Ayurveda, Madhav Vilas Palace, Jorawar Singh Gate, Amer Road, JAIPUR - 302002 (RAJASTHAN) INDIA

Primary Sponsor

Primary Sponsor Details	
Name	National Institute of Ayurveda
Address	Madhav Vilas Palace, Jorawar Singh Gate, Amer Road JAIPUR - 302002 (RAJASTHAN) INDIA
Type of Sponsor	Government medical college

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
Prof Dr Sanjeev Sharma	National Institute of Ayurveda	OPD No 1, Department of Shalya Tantra, Ground floor, Madhav Vilas Palace, Jorawar Singh Gate, Amer Road JAIPUR - 302002 (RAJASTHAN) INDIA Jaipur RAJASTHAN	09418079691 profsanjeevhp@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee National Institute of Ayurveda Madhav Vilas Palace, Amer Road, Jaipur	Approved	22/05/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Healthy Human Volunteers

Intervention / Comparator Agent

Type	Name	Details
Intervention	Guduchi Ghana Vati	Each Guduchi Ghana Vati contains Guduchi Ghana (Tinospora cordifolia) 500 mg with preservatives and excipients Dosage and Treatment Duration: 2 tablets twice daily orally after meals with water for 45 days
Comparator Agent	NIL	Dosage and Treatment Duration: Subjects in this group will not be given any medicine

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	70.00 Year(s)
Gender	Both
Details	1. Healthy, Male or Female subjects between the age group of 18 years to 70 years (both inclusive). Healthy individuals will be considered as those who do not have any acute medical condition or chronic medical/surgical condition that requires either immediate or continuous medical monitoring or treatment. 2. Subjects who are ready to provide written informed consent and who are ready to willingly participate and follow the protocol requirements of the clinical study.

Exclusion Criteria

Exclusion Criteria	
Details	1. Pregnant and Lactating females 2. Subjects who have been confirmed of having COVID-19 and have been isolated for its treatment. Subjects having recently suffered and recovered of COVID-19 will also be excluded from the study 3. Subjects having any medical or surgical condition that would require immediate medical or surgical intervention at the time of screening 4. Subjects having immune compromised status like HIV, Hepatitis, Tuberculosis and Cancer etc. 5. Subjects taking steroid treatment and or any kind of immunosuppressive therapy 6. Subjects participating in any other clinical study or having participated in any other study 3 months prior to screening in the present study. 7. Other conditions, which in the opinion of the investigators makes the patient unsuitable for enrolment or could interfere in adherence to of the study protocol

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Not Applicable
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
Comparative assessment of incidence of COVID-19 in subjects taking GUDUCHI GHANA VATI and those not taking it over a period of 45 days	(day-5, day 0, day-15, day-30, day-45)

Secondary Outcome

Outcome	Timepoints
1. Comparative assessment of incidence of other non COVID-19 infections in both the groups 2. Comparative assessment of severity of COVID-19 in both the groups. 3. Comparative assessment of number of subjects requiring hospitalization, number of days of hospitalization, ICU admission, Ventilator support and mortality rate. 4. Global assessment of overall change as per the investigator 5. Safety assessment by evaluation of occurrence of AE/SAE	(day-5, day 0, day-15, day-30, day-45)

Target Sample Size	**Total Sample Size=**12000

	Sample Size from India=12000 **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/ Phase 3
Date of First Enrollment (India)	03/06/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**8 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	NOT YET DONE
Brief Summary	It is an open label, multi centric, randomized, comparative, prospective, interventional community based clinical study to evaluate safety and efficacy of Guduchi Ghana Vati as a preventive remedy on healthy individuals in pandemic of COVID-19. The trial will be completed in 12000 subjects in 6 centers across India. Subjects from group A will be given Guduchi Ghana Vati in a dose of two tablets twice daily orally after meals with water for 45 days. Subjects from group B will not be given any intervention. The primary objectives of the study will be comparative assessment of incidence of COVID-19 in subjects taking GUDUCHI GHANA VATI and those not taking it over a period of 45 days. Secondary objectives will be comparative assessment of incidence of other non COVID-19 infections in subjects taking GUDUCHI GHANA VATI and those not taking it over a period of 45 days, comparative assessment of severity of COVID-19 (when it occurs) in subjects taking GUDUCHI GHANA VATI and those not taking it. Severity will be graded as per the attached ordinal scale for clinical improvement of COVID-19 published by WHO, comparative assessment of number of subjects requiring hospitalization, number of days of hospitalization, number of subjects requiring ICU admission and number of subjects requiring Ventilator support and mortality rate, global assessment of overall change as per the investigator and safety assessment by evaluation of occurrence of AE/SAE on day-5, day 0, day-15, day-30 and day-45.