Clinical Trial Details (PDF Generation Date :- Sat, 30 Sep 2023 11:40:15 GMT)

CTRI Number	CTRI/2020/05/025088 [Registered on: 09/05/2020] - **Trial Registered Prospectively**
Last Modified On	08/05/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug Ayurveda Preventive
Study Design	Randomized, Parallel Group Trial
Public Title of Study	Study of GUDUCHI TABLET on healthy individuals to prevent covid 19.
Scientific Title of Study	Observational Study of GUDUCHI TABLET intake as a preventive measure in pandemic of COVID-19 – An open label, Randomized, Controlled, Prospective, Interventional, Community-based Clinical study on healthy subjects

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 B vankatshwarlu
Designation	Research officer(Ayu)
Affiliation	Regional ayurveda research instutute vijayawada
Address	Regional Ayurveda Research Institute for Skin disorders, New Rajeev nagar, Payakapuram Vjayawada. Krishna ANDHRA PRADESH 520015 India
Phone	6301340787
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Details Contact Person (Scientific Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
> Ministry of Ayush government of India

Primary Sponsor

Primary Sponsor Details	
Name	central council for rsearch in ayurvedic sciences
Address	61-65, opp. D Block, Janakpuri Institutional Area, Janakpuri, New Delhi, Delhi 110058
Type of Sponsor	Research institution

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 K Anumol	Regional Ayurveda research institute Vijayawada	Regional Ayurveda research institute for skin disorders , new rajeev nagar Vijayawada Krishna ANDHRA PRADESH	8075021635 dranumolk@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional ethics committee Vijayawada	Approved	05/05/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Participant will select from area where atleast one covid 19 positive patient available

Intervention / Comparator Agent

Type	Name	Details
Intervention	Guduchi tablet	Tab Guduchi 500mg twice daily for one month
Comparator Agent	nil	nil

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	68.00 Year(s)
Gender	Both
Details	1.Adult Male or Female subjects above the age of 18 years to 68 years. 2.Subjects who are froma community where at least 1 confirmed case is already identified. 3.Subjects who are ready to provide written/digital informed consent and who are willing to participate and follow the protocol requirements of the clinical study

Exclusion Criteria

Exclusion Criteria	
Details	1.Pregnant and Lactating females

	2.Known cases of uncontrolled Diabetes and Hypertension. 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, 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 1 month prior to screening in the present study. 7.Subjects having a past history of allergy to any medicine that is part of the Ayurvedic intervention. 8.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	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
1. Comparative assessment of occurrence of COVID-19 infection in healthy volunteers in community having at least 1 confirmed case already identified with control arm of Standard Prophylactic Care	15th day, 30th day, 45th day

Secondary Outcome

Outcome	Timepoints
1. Comparative assessment of severity of Covid-19 infection in subjects taking GUDUCHI TABLET and those not taking it in following situations: a) Assessment of subjects not requiring hospitalization b) Severity of symptoms of hospitalized patients in wards c) Patients requiring ICU admission / Ventilator support 2. Global assessment of overall change as per the investigator (Efficacy assessment)	15th day , 30th day and 45 th day

Target Sample Size	**Total Sample Size=**1200 **Sample Size from India=**1200 **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 1/ Phase 2
Date of First Enrollment (India)	20/05/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**6 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of	Not Yet Recruiting

Trial (India)	
Publication Details	nil
Brief Summary	**There is no available vaccine against COVID-19 infections and no drug with proven clinical efficacy, although there are several candidates that might be effective in prevention or treatment. Encouragingly, the response from the research community to the pandemic of Coronavirus disease 2019 (COVID-19) has been vigorous.Guduchi is Rasayana drug which improves immunity. In This study will give Guduchi tab 500mg twice daily for one month to healthy individuals to prevent Covid 19. We are selecting the patient from community where atleast one covid 19 patient is present.The possible outcomes of thestudy will be Primary outcome Comparative assessment of occurrence of COVID-19 infection in healthy volunteers in community having at**

least 1 confirmed case already identified with control arm of Standard Prophylactic

Care and Secondary outcomev will be

Comparative assessment of severity of Covid-19 infection in subjects taking

Guduchi Tablet and those not taking it in following situations:

a) Assessment of subjects not requiring hospitalization

b) Severity of symptoms of hospitalized patients in wards

c) Patients requiring ICU admission / Ventilator support

2. Global assessment of overall change as per the investigator (Efficacy assessment)

3. Safety assessment by evaluation of occurrence of AE/SAE due to consumption

of Ayurveda Intervention