Clinical Trial Details (PDF Generation Date :- Sun, 06 Dec 2020 01:30:51 GMT)

CTRI Number	CTRI/2020/05/025298 [Registered on: 21/05/2020] - **Trial Registered Prospectively**
Last Modified On	21/05/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Siddha
Study Design	Non-randomized, Active Controlled Trial
Public Title of Study	Siddha Intervention Population Study.
Scientific Title of Study	A prospective non-randomised open label controlled interventional study on the e ffe ct of Siddha intervention as a prophylactic measure among high risk population (Health Care Workers/ Containment Zone population) exposed to COVID 19

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	DrKKanakavalli
Designation	Director General
Affiliation	siddha central research Institute
Address	Anna Hospital Campus Arumbakkam Chennai TAMIL NADU 600106 India
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Details Contact Person (Scientific Query)

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Details Contact Person (Public Query)

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Source of Monetary or Material Support

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> MINISTRY OF AYUSH. AYUSH BHAWAN, B-Block, GPO COMPLEX,. INA COLONY, NEW DELHI - 11-0023

Primary Sponsor

Primary Sponsor Details	
Name	Central council for research in Siddha
Address	Central Council for research in Siddha Siddha central research institute Anna hospital campus Arumbakkam Chennai
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
PSathiyarajeswaran	siddha central research institute	Departmrnt of clinical research Siddha central research Institute Chennai TAMIL NADU	8754495186 p.sathiyarajeswaran@gov.in

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
SIDDHACENTRALRESEARCH INSTITUTE	Approved	08/05/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	B972

Intervention / Comparator Agent

Type	Name	Details
Intervention	Kabasurakudineer Nilavembukudineer	Siddha official formulation once daily for 14 days.
Comparator Agent	Personal Sanitation and Environmental Sanitataion	Sanitisers Handwash Masks Gloves for 6 months

Inclusion Criteria

Inclusion Criteria	
Age From	5.00 Year(s)
Age To	68.00 Year(s)
Gender	Both
Details	1. Adult Male or Female subjects above the age of 5 years to 68 years 2. Subjects who are from a 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	Pregnant and Lactating females Known cases of uncontrolled Diabetes and Hypertension COPD or Lung related diseases 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 Siddha 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	1stweek 2ndweek 3rd week and 4th week

Secondary Outcome

Outcome	Timepoints
Assessment of side effects non hospitalization no severe symptoms no ventilatory support no of days in ICU	1stweek 2ndweek 3rd week and 4th week

Target Sample Size	**Total Sample Size=**21500 **Sample Size from India=**21500 **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	N/A
Date of First Enrollment (India)	25/05/2020
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 Trial (India)	Not Yet Recruiting
Publication Details	NIL
Brief Summary	Ayush Ministry during March 2020 released an advisory to Mitigate Covid19 with AYUSH intervention Kabasurakudineer and Nilavembukudineer have been listed among prophylactics and suspected cases. AYUSH also advised all research councils to test the Intervention for their prophylactic effect. This - Non Randomised open labelled prophylactic intervention study will help to cull out the real effect of this drug.