Clinical Trial Details (PDF Generation Date :- Fri, 14 Aug 2020 10:51:05 GMT)

CTRI Number	CTRI/2020/06/025769 [Registered on: 09/06/2020] - **Trial Registered Prospectively**
Last Modified On	23/07/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Siddha Preventive
Study Design	Non-randomized, Multiple Arm Trial
Public Title of Study	A prophylactic interventional study to determine the possible protective effect of Siddha Polyherbal formulation Kabasura Kudineer against the COVID 19 on intermittent, month-long consumption by public with close contacts to COVID patients and frontline workers in Tamil Nadu, India
Scientific Title of Study	A prospective Non randomized open label controlled intervention study on the effect of Polyherbal Siddha formulation Kabasura kudineer 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	Dr R Meenakumari
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
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Details Contact Person (Public Query)

Details Contact Person (Public Query)	
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Source of Monetary or Material Support

Source of Monetary or Material Support
> National Institute of Siddha, Tambaram Sanatorium, chennai - 47

Primary Sponsor

Primary Sponsor Details	
Name	National institute of Siddha Ministry of AYUSH
Address	National institute of Siddha, tambaram sanatorium, chennai - 47
Type of Sponsor	Research institution and hospital

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 Suresh	National Institute of Siddha	GST Road Tambaram Sanatorium chennai 47 Kancheepuram TAMIL NADU	9962571137 drsureshherbal@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethical Committee	Approved	09/05/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Highrisk population and frontline workers of COVID19 Pandemic

Intervention / Comparator Agent

Type	Name	Details
Intervention	Kabasura kudineer	5- 10gms of Kabasura kudineer drug boiled with 240ml of water will be reduced to 60 ml, filtered and Consumed within 3 hours. Concoction will be freshly prepared for every dose. Time of Administration: This dose will be administered once a day just before or after food.
Comparator Agent	Standard of Care	General public and frontline workers who have taken/given Allopathic Standard of Care like Vitamins and/or other drugs for Covid prevention.

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	80.00 Year(s)
Gender	Both
Details	All the willing frontline health workers, police personnel and other

	public servants inclusive of those with direct / primary contacts with COVID positives (High risk and moderate risk exposures).

Exclusion Criteria

Exclusion Criteria	
Details	Not willing to sign informed consent. Subjects taking Steroid treatment and or any kind of immunosuppressive therapy Subjects participating in any other clinical study or having participated in any other study 1 month prior to screening in the present study.

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
Percentage of participants protected during the outbreak of COVID 19 compared between the Kabasura Kudineer taken and Standard of Care taken groups	Assessment will be done at Baseline and 30th day from the start of Prophylactic intervention.

Secondary Outcome

Outcome	Timepoints
General and specific health status as assessed. ? Immune Status and Function as assessed by ISQ ? Progression of disease in the participants who turned COVID 19 positive	6 months

Target Sample Size	**Total Sample Size=**40000 **Sample Size from India=**40000 **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)	15/06/2020
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)	Open to Recruitment
Publication Details	Not yet
Brief Summary	As there is a sudden outbreak of Novel coronavirus all over the world there is a need of drug to prevent the COVID infection from direct contact persons who are in high , moderate,Low risks of the disease. To document the prophylatic efficacy of the drug Kabasura kudineer among the high risk population, Moderate risk and low risk frontline workers. This study will be conducted as Non randomized study among the high, moderate and low risk frontline workers in Tamil nadu.