Clinical Trial Details (PDF Generation Date :- Fri, 14 Aug 2020 09:48:47 GMT)

CTRI Number	CTRI/2020/06/025768 [Registered on: 09/06/2020] - **Trial Registered Prospectively**
Last Modified On	09/06/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug Siddha
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	An open label Randomized Controlled Clinical trial to Evaluate the Safety and Efficacy of selected Siddha formulations in patients diagnosed with COVID-19
Scientific Title of Study	An open label Randomized Controlled Clinical trial to Evaluate the Safety and Efficacy of selected Siddha formulations in patients diagnosed with 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 MEENAKUMARI R
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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
Address	National Institute of Siddha, Tambaram Sanatorium,Chennai -47
Type of Sponsor	Research institution and hospital

Details of Secondary Sponsor

Name	Address
Chengalpattu Medical College Hospital	Chengalpattu Medical College Hospital, Chengalpattu - 603001.

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr G J CHRISTIAN	Chengalpattu Medical College Hospital	Chengalpattu Medical College Hospital, Chengalpattu - 603001. Kancheepuram TAMIL NADU	9962545930 christianvijila@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Instuitional Ethical Committee	Approved	26/05/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Coronavirus infection, unspecified

Intervention / Comparator Agent

Type	Name	Details
Intervention	Kabasura kudineer, Amukkara churnam and Nellikai ilagam	Kabasura kudineer: 10gms of drug boiled with 240ml of water will be reduced to 60 ml, filtered and consumed within 3 hours. Decoction will be freshly prepared for every dose. Convalescent medicine namely NELLIKAI ILAGAM 5gm BD and AMUKKARA CHURNAM 2gm BD. The intervention will be administered for 30 days or till the RT PCR becomes negative whichever is earlier
Comparator Agent	nil	NIL

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	85.00 Year(s)

Gender	Both
Details	Male, Female and Transgenders. ? Age between 18 to 85 years ? COVID 19 positive asymptomatic / pre symptomatic, mild and moderately symptomatic patients. ? Willing to consent to the study.

Exclusion Criteria

Exclusion Criteria	
Details	High risk groups-Patients with other severe medical conditions requiring intensive management.s Other viral pneumonia Patients who have received organ transplantation in the past 6 months or planning surgery Patients with severe or critical covid-19 infections.

Method of Generating Random Sequence	Adaptive randomization, such as minimization
Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
Primary Outcome would be measured through Resolution of symptoms and Recovery of patients from COVID 19 disease compared to patients taking only standard of care treatment at specific time points. RT PCR conversion within first week with accelerated recovery as compared to control group	6 months

Secondary Outcome

Outcome	Timepoints
Possible reduction of viral load data in subsets of both groups both at baseline and at 7 days, and14 days or at recovery or 30 days whichever is earlier.. ? Sub group analysis for male, female and Age groups will also be studied in each group. Number of days on treatment before recovery and case fatality rate if any will be documented.	6 MONTHS

Target Sample Size	**Total Sample Size=**200 **Sample Size from India=**200 **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
Date of First Enrollment (India)	20/06/2020
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)	Not Yet Recruiting
Publication Details	NIL
Brief Summary	COVID 19 has almost entered every part of the world. Treatments proposed is ineffective or minimally effective. Hence, it is important to find drugs in appropriate time. Kabasura kudineer is a Siddha drug proposed by entire Siddha fraternity to combat COVID 19 disease after analyzing its

nature. It is proven to be effective in preclinical analysis. It is to be analysed clinically through this study.