Clinical Trial Details (PDF Generation Date :- Fri, 14 Aug 2020 11:36:33 GMT)

CTRI Number	CTRI/2020/06/025763 [Registered on: 09/06/2020] - **Trial Registered Prospectively**
Last Modified On	06/08/2020
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	A Randomized controlled Clinical Trial to determine the efficacy of Siddha drugs in COVID 19 patients
Scientific Title of Study	A Randomized controlled Clinical Trial to determine the complementary effect of selected Siddha formulations in facilitating the possibility of accelerated recovery in COVID 19 patients.

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	Meenakumari R
Designation	Director
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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
> 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
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 M Meenakshi Sundaram	SRM Medical college Hospital and Research centre	SRM Medical college Hospital and Research centre, Kaattankulathur, Chengalpattu Dt., Tamilnadu, India. Kancheepuram TAMIL NADU	9940266442 mmssiddha@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee	Approved	20/05/2020	No
SRMIST Ethics Committee	Approved	06/07/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Coronavirus as the cause of diseases classified elsewhere

Intervention / Comparator Agent

Type	Name	Details
Intervention	Kabasura kudineer, Nilavembu kudineer, Amukra churnam, Thalisadhichurnam, Adathodai Manappagu, Brahmanada Bhairavam Pills, Thippili Rasayanam, Maldevi Chenduram, Adathodai Kudineer, Nochi Kudineer, Thirikadugu Churnam, Adathodai Manappagu and Herbal Tea	Thirikadugu Churnam, Adathodai Kudineer, Nochi Kudineer, Maldevi chenduram are for Moderate and Severe COVIDs and Nilavembu kudineer, Adathodai Manappagu, Brahmanada bairavam are exclusively for Mild covids
Comparator Agent	Standard of Care	Standard of Care with or without Siddha Placebo

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 and severely symptomatic patients. ? Willing to consent to the study.

Exclusion Criteria

Exclusion Criteria	
Details	High risk groups (Patients with Complications of Diabetes, Heart diseases, Cancer and Pregnancy) ? Multi organ failure Syndrome (MODS). ? Patients participating in other COVID 19 trials.

Method of Generating Random Sequence	Adaptive randomization, such as minimization
Method of Concealment	Sequentially numbered, sealed, opaque envelopes
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
Primary Outcome would be measured through Reduction of symptoms and Recovery of patients from COVID 19 disease in a time bound manner.Conversion of RT PCR negative within first week of accelerated recovery	6 months

Secondary Outcome

Outcome	Timepoints
Possible reduction of viral load data in subjects both at baseline and at 7 days, and 14 days or at recovery or 30 days whichever is earlier.. ? Number of days on treatment before recovery and Case fatality rate will also be noted. ? Reduction in Signs and symptoms like Fever, cough, breathlessness, and improvement in O2 saturation (SpO2) and PaO2/FiO2 becoming 300mg/Hg in patients with severe grade and ARDS.	6 MONTHS

Target Sample Size	**Total Sample Size=**150 **Sample Size from India=**150 **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)	17/07/2020
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	Nil
Brief Summary	As there is a sudden outbreak of Novel Coronavirus disease all over the world. As there is no direct drug against the disease spread, it is a time needed action of usage of AYUSH drugs in management. Various drugs have cited by AYUSH ministry and State government for management of the disease spread like Kabasura kudineer, Amukkara choornam etc. This study will be

conducted based on the Prelimmary analysis and literature evidence of drugs namely Kabasura kudineer, Amukkara choornam, Thalisathi choornam and Adathodai manapaggu among the sample consists of 18 years and above COVID-19 – RT PCR +ve patients declared by Tamil Nadu Government accredited labs admitted to COVID 19 ward at SRMMCH / NIS or quarantined Govt. facilities or at home quarantine. The subjects will be randomly allocated to both the groups. This study is carried out to document scientifically the therapeutic efficacy of these drugs against Novel Corona virus disease.