



Clinical Trial Details (PDF Generation Date :- Wed, 07 Jun 2023 17:46:46 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 effect 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
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	Phone	
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Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
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Email	drkkanakavalli@gmail.com			
Source of Monetary or Material Support	Source of Monetary or Material Support			
	> 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	Department 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 Sanitaitaion	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		



	<p>Tuberculosis Cancer etc.</p> <p>5. Subjects taking Steroid treatment and or any kind of immunosuppressive therapy</p> <p>6. Subjects participating in any other clinical study or having participated in any other study 1 month prior to screening in the present study.</p> <p>7. Subjects having a past history of allergy to any medicine that is part of the Siddha intervention.</p> <p>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</p>	
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	<p>Total Sample Size=21500</p> <p>Sample Size from India=21500</p> <p>Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials</p> <p>Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials</p>	
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	<p>Years=0</p> <p>Months=6</p> <p>Days=0</p>	
Recruitment Status of Trial (Global)	Not Applicable	
Recruitment Status of Trial (India)	Not Yet Recruiting	
Publication Details	NIL	
Brief Summary	<p>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.</p>	