



Clinical Trial Details (PDF Generation Date :- Sat, 30 Sep 2023 10:50:42 GMT)

<b>CTRI Number</b>	CTRI/2020/06/025761 [Registered on: 09/06/2020] - <b>Trial Registered Prospectively</b>	
<b>Last Modified On</b>	22/04/2021	
<b>Post Graduate Thesis</b>	No	
<b>Type of Trial</b>	Observational	
<b>Type of Study</b>	Cross Sectional Study	
<b>Study Design</b>	Non-randomized, Multiple Arm Trial	
<b>Public Title of Study</b>	Population based cross sectional study for COVID 19 prophylaxis with Polyherbal Siddha formulation Kabasura Kudineer / Nilavembu kudineer in containment zones and non containment zones during 2020 pandemic in Tamil Nadu, South India	
<b>Scientific Title of Study</b>	Population based cross sectional study for COVID 19 prophylaxis with Polyherbal Siddha formulation Kabasura Kudineer / Nilavembu kudineer in containment zones and non containment zones during 2020 pandemic in Tamil Nadu, South India	
<b>Secondary IDs if Any</b>	<b>Secondary ID</b>	<b>Identifier</b>
	NIL	NIL
<b>Details of Principal Investigator or overall Trial Coordinator (multi-center study)</b>	<b>Details of Principal Investigator</b>	
	<b>Name</b>	Dr R Meenakumari
	<b>Designation</b>	Director
	<b>Affiliation</b>	National institute of Siddha
	<b>Address</b>	National institute of siddha tambaram sanatorium National institute of siddha tambaram sanatorium Kancheepuram TAMIL NADU 600047 India
	<b>Phone</b>	9176534465
	<b>Fax</b>	
	<b>Email</b>	nischennaisiddha@yahoo.co.in
	<b>Details Contact Person (Scientific Query)</b>	<b>Details Contact Person (Scientific Query)</b>
<b>Name</b>		Dr G J Christian
<b>Designation</b>		Head of the Department , department of Noi Naadal
<b>Affiliation</b>		National institute of Siddha
<b>Address</b>		national institute of siddha tambaram sanatorium national institute of siddha tambaram sanatorium Kancheepuram TAMIL NADU 600047 India
<b>Phone</b>		9962545930
<b>Fax</b>		
<b>Email</b>		christianvijila@gmail.com
<b>Details Contact Person (Public Query)</b>	<b>Details Contact Person (Public Query)</b>	
	<b>Name</b>	Dr G J Christian
	<b>Designation</b>	Head of the Department , department of Noi Naadal
	<b>Affiliation</b>	National institute of Siddha
	<b>Address</b>	national institute of siddha tambaram sanatorium national institute of siddha tambaram sanatorium Kancheepuram TAMIL NADU 600047



	India			
<b>Phone</b>	9962545930			
<b>Fax</b>				
<b>Email</b>	christianvijila@gmail.com			
<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>			
	> National institute of Siddha, Tmbaram Sanatorium, chennai - 47.			
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
<b>Name</b>	National Institute of Siddha			
<b>Address</b>	National institute of Siddha, Tambaram Sanatorium, Chennai - 47			
<b>Type of Sponsor</b>	Research institution and hospital			
<b>Details of Secondary Sponsor</b>	<b>Name</b>	<b>Address</b>		
	NIL	NIL		
<b>Countries of Recruitment</b>	<b>List of Countries</b>			
	India			
<b>Sites of Study</b>	<b>Name of Principal Investigator</b>	<b>Name of Site</b>	<b>Site Address</b>	<b>Phone/Fax/Email</b>
	Christian G J	Tambaram Taluk	Mudichur, Rajakilpakkam, Hastinapuram, Pammal , Tambaram Kancheepuram TAMIL NADU	9962545930  christianvijila@gmail.com
<b>Details of Ethics Committee</b>	<b>Name of Committee</b>	<b>Approval Status</b>	<b>Date of Approval</b>	<b>Is Independent Ethics Committee?</b>
	Institutional Ethical Committee	Approved	09/05/2020	No
<b>Regulatory Clearance Status from DCGI</b>	<b>Status</b>		<b>Date</b>	
	Not Applicable		No Date Specified	
<b>Health Condition / Problems Studied</b>	<b>Health Type</b>		<b>Condition</b>	
	Healthy Human Volunteers		COVID Prophylaxis	
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>	
	Intervention	Nil	Nil	
	Comparator Agent	Nil	Nil	
<b>Inclusion Criteria</b>	<b>Inclusion Criteria</b>			
	<b>Age From</b>	18.00 Year(s)		
	<b>Age To</b>	75.00 Year(s)		
	<b>Gender</b>	Both		
	<b>Details</b>	a) Laboratory confirmed COVID-19 with or without symptoms b) Those who are to be excluded in the study, as evaluated by the investigators. c) Persons intaking Kabasura kudineer / Nilavembu kudineer procured from non GMP certified pharma companies. 7 d) Persons with poor drug compliance		
<b>Exclusion Criteria</b>	<b>Exclusion Criteria</b>			
	<b>Details</b>	a) Laboratory confirmed COVID-19 with or without symptoms b) Those who are to be excluded in the study, as evaluated by the investigators. c) Persons intaking Kabasura kudineer / Nilavembu kudineer procured from non GMP certified pharma companies.		



	7 d) Persons with poor drug compliance				
<b>Method of Generating Random Sequence</b>	Not Applicable				
<b>Method of Concealment</b>	Not Applicable				
<b>Blinding/Masking</b>	Not Applicable				
<b>Primary Outcome</b>	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td>COVID-19 Test Positivity / Negativity upto 31 days follow up.</td> <td>COVID-19 Test Positivity / Negativity upto 31 days follow up.</td> </tr> </tbody> </table>	Outcome	Timepoints	COVID-19 Test Positivity / Negativity upto 31 days follow up.	COVID-19 Test Positivity / Negativity upto 31 days follow up.
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<b>Secondary Outcome</b>	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td>General and specific health status as described above. Immune Status and Function as assessed by ISQ</td> <td>3 months</td> </tr> </tbody> </table>	Outcome	Timepoints	General and specific health status as described above. Immune Status and Function as assessed by ISQ	3 months
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General and specific health status as described above. Immune Status and Function as assessed by ISQ	3 months				
<b>Target Sample Size</b>	<b>Total Sample Size=10000</b> <b>Sample Size from India=10000</b> <b>Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials</b> <b>Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials</b>				
<b>Phase of Trial</b>	N/A				
<b>Date of First Enrollment (India)</b>	15/06/2020				
<b>Date of First Enrollment (Global)</b>	No Date Specified				
<b>Estimated Duration of Trial</b>	<b>Years=0</b> <b>Months=3</b> <b>Days=0</b>				
<b>Recruitment Status of Trial (Global)</b>	Not Applicable				
<b>Recruitment Status of Trial (India)</b>	Suspended				
<b>Publication Details</b>	Not yet				
<b>Brief Summary</b>	As there was a sudden pandemic outbreak of Novel Corona virus disease all over the World, various herbal remedies have been suggested by the AYUSH ministry and the state government of Tamilnadu for prophylaxis. In need to document the various herbal remedies along with Kabasura kudineer and Nilavembu kudineer in various containment zones and Non- containment zones a questionnaire based population study survey will be conducted.				