## Clinical Trial Details (PDF Generation Date :- Mon, 19 Jul 2021 23:38:37 GMT)

<table>
<thead>
<tr>
<th>CTRI Number</th>
<th>CTRI/2020/08/027286 [Registered on: 21/08/2020] - Trial Registered Prospectively</th>
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<tbody>
<tr>
<td>Last Modified On</td>
<td>13/04/2021</td>
</tr>
<tr>
<td>Post Graduate Thesis</td>
<td>No</td>
</tr>
<tr>
<td>Type of Trial</td>
<td>Interventional</td>
</tr>
<tr>
<td>Type of Study</td>
<td>Siddha</td>
</tr>
<tr>
<td>Study Design</td>
<td>Randomized, Parallel Group, Placebo Controlled Trial</td>
</tr>
<tr>
<td>Public Title of Study</td>
<td>Effectiveness of Siddha Medicines Kabasura Kudineer and Nilavembu Kudineer in the Management of Symptomatic COVID 19 patients</td>
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<tr>
<td>Scientific Title of Study</td>
<td>A Controlled Double Blinded RCT to Evaluate the effectiveness of Siddha medicines, Kaba Sura Kudineer(KSK) &amp;Nilavembu Kudineer(NVK) along with Standard Allopathy Treatment in the management of symptomatic COVID 19 patients</td>
</tr>
<tr>
<td>Secondary IDs if Any</td>
<td>Secondary ID</td>
</tr>
<tr>
<td></td>
<td>NIL</td>
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</table>

### Details of Principal Investigator

<table>
<thead>
<tr>
<th>Name</th>
<th>Dr R MANICKAVASAGM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designation</td>
<td>Research Officer - Siddha</td>
</tr>
<tr>
<td>Affiliation</td>
<td>Siddha Clinical Research Unit, New Delhi</td>
</tr>
<tr>
<td>Address</td>
<td>Siddha Clinical Research Unit, Room.No 108, First Fl.M.S.Office Building, Safdarjung Hospital Campus, New Delhi - 29. Siddha Clinical Research Unit, Room.No 108, First Fl.M.S.Office Building, Safdarjung Hospital Campus, New Delhi - 29, South DELHI 110029 India</td>
</tr>
<tr>
<td>Phone</td>
<td>9884166739</td>
</tr>
<tr>
<td>Fax</td>
<td></td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:nismanick@gmail.com">nismanick@gmail.com</a></td>
</tr>
</tbody>
</table>

### Details Contact Person (Scientific Query)

<table>
<thead>
<tr>
<th>Name</th>
<th>Dr ANURAG SRIVASTAVA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designation</td>
<td>Associate Professor</td>
</tr>
<tr>
<td>Affiliation</td>
<td>Government Institute of Medical Sceinces,</td>
</tr>
<tr>
<td>Address</td>
<td>Government Institute of Medical Sceinces, Gautam Buddha Nagar, Greater Noida. UTTAR PRADESH. Government Institute of Medical Sceinces, Gautam Buddha Nagar, Greater Noida. UTTAR PRADESH. Gautam Buddha Nagar UTTAR PRADESH 201310 India</td>
</tr>
<tr>
<td>Phone</td>
<td>730384221</td>
</tr>
<tr>
<td>Fax</td>
<td></td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:dranurag23@gmail.com">dranurag23@gmail.com</a></td>
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### Details Contact Person (Public Query)

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</tr>
</tbody>
</table>
**Source of Monetary or Material Support**

**Primary Sponsor**
- **Name**: Government Institute of Medical Sciences
- **Address**: Gautam Buddha Nagar, Greater Noida, UP
- **Type of Sponsor**: Government medical college

**Details of Secondary Sponsor**
- **Name**: Central Council for Research in Siddha
- **Address**: SCRI Building, Govt Aringar anna Hospital Campus, Arumbakkam, Chennai, Tamilnadu-106

**Countries of Recruitment**
- **List of Countries**: India

**Sites of Study**

<table>
<thead>
<tr>
<th>Name of Principal Investigator</th>
<th>Name of Site</th>
<th>Site Address</th>
<th>Phone/Fax/Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. MANICKAVASAGAM</td>
<td>Government Institute of Medical Sciences</td>
<td>Gautam Buddha Nagar, Greater Noida, UP</td>
<td>9884166739 <a href="mailto:nismanick@gmail.com">nismanick@gmail.com</a></td>
</tr>
</tbody>
</table>

**Details of Ethics Committee**

<table>
<thead>
<tr>
<th>Name of Committee</th>
<th>Approval Status</th>
<th>Date of Approval</th>
<th>Is Independent Ethics Committee?</th>
</tr>
</thead>
<tbody>
<tr>
<td>GIMS IEC &amp; SCRU IHEC</td>
<td>Approved</td>
<td>08/08/2020</td>
<td>No</td>
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<tr>
<td>IHEC SCRU</td>
<td>Approved</td>
<td>02/11/2020</td>
<td>No</td>
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</tbody>
</table>

**Regulatory Clearance Status from DCGI**
- **Status**: Not Applicable
- **Date**: No Date Specified

**Health Condition / Problems Studied**
- **Health Type**: Coronavirus as the cause of diseases classified elsewhere

**Intervention / Comparator Agent**

<table>
<thead>
<tr>
<th>Type</th>
<th>Name</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td>Kaba sura Kudineer</td>
<td>60 ml twice a day - Morning and Night After food for 10 days</td>
</tr>
<tr>
<td>Intervention</td>
<td>Nilavembu Kuidneer</td>
<td>60 ml twice a day - Morning and Night After food for 10 days</td>
</tr>
<tr>
<td>Comparator Agent</td>
<td>Decaffeinated Tea</td>
<td>60 ml twice a day - Morning and Night After food for 10 days</td>
</tr>
</tbody>
</table>

**Inclusion Criteria**

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age From</td>
<td>18.00 Year(s)</td>
</tr>
<tr>
<td>Age To</td>
<td>68.00 Year(s)</td>
</tr>
<tr>
<td>Gender</td>
<td>Both</td>
</tr>
</tbody>
</table>
| Details | 1. Laboratory Confirmed COVID – 19 with Mild and Moderate symptoms (as per ICMR Guidelines) with 2:1 Ratio in each group with proper representation of Age group/Sex. 2. Aged 18-65 years 3. Consenting to participate in the study and sign the
Exclusion Criteria

Details

1. Patients with severe primary respiratory disease or other pathogenic microbial pneumonia
2. Patient with Uncontrolled DM (? 350 mgs Fasting Sugar)
   SevereHT(180/120 mmHg as per JNC 8 Guidelines), Chronic BA(? 5 years Based on Clinical History), Renal Dysfunction (Known CKD ? 5 years eGFR Stage ? 3 as per NKA guidelines)
3. Pregnant and Lactating mothers
4. Patients with other systemic malignant diseases such as malignant tumors, mental illnesses, which the researchers consider unsuitable for participation in the study
5. People who have history of allergic to Siddha medicine or intolerant to taking medication
6. Patients participating in other COVID-19 clinical trials

Method of Generating Random Sequence

Computer generated randomization

Method of Concealment

Sequently numbered, sealed, opaque envelopes

Blinding/Masking

Participant and Investigator Blinded

Primary Outcome

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Timepoints</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Reduction in Viral load of SARS-CoV-2 at the end of treatment</td>
<td>10 Days</td>
</tr>
<tr>
<td>2. Time taken to convert Patient from symptomatic to Asymptomatic based on Reduction in clinical symptoms like fever, cough and breathlessness</td>
<td></td>
</tr>
<tr>
<td>3. Effect of drugs inflammatory markers (IL6,) at the end of treatment.</td>
<td></td>
</tr>
<tr>
<td>4. Reduction in use of Intensive Supportive Care</td>
<td></td>
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Secondary Outcome

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Timepoints</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Reduction in incidence of complications (ARDS, other systematic complications)</td>
<td></td>
</tr>
<tr>
<td>2. Reduction in hospital stay time.</td>
<td></td>
</tr>
<tr>
<td>3. Differentiation in Laboratory markers (Hematological &amp; Bio – Chemical Markers)</td>
<td></td>
</tr>
<tr>
<td>4. Adverse events/effects Siddha-based measurements</td>
<td></td>
</tr>
<tr>
<td>5. Siddha Udaliyal assessment by using YI Tool</td>
<td>10 Days</td>
</tr>
</tbody>
</table>

Target Sample Size

Total Sample Size = 120
Sample Size from India = 120
Final Enrollment numbers achieved (Total) = 120
Final Enrollment numbers achieved (India) = 120

Phase of Trial

Phase 2

Date of First Enrollment (India)

22/08/2020

Date of First Enrollment (Global)

No Date Specified

Estimated Duration of Trial

Years = 0
Months = 4
Days = 0

Recruitment Status of

Not Applicable
<table>
<thead>
<tr>
<th>Trial (Global)</th>
<th>Completed</th>
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<tbody>
<tr>
<td>Recruitment Status of Trial (India)</td>
<td>Protocol of the Study Published in BMC Trials Journal.</td>
</tr>
<tr>
<td>Publication Details</td>
<td>Coronavirus disease 2019 (COVID-19) is a respiratory tract infection caused by a newly emergent coronavirus, SARS-CoV-2, that was first recognized in Wuhan, China, in December 2019. While most people with COVID-19 develop mild or uncomplicated illness, approximately 14% develop severe disease requiring hospitalization and oxygen support and 5% require admission to an intensive care unit. (1) In severe cases, COVID-19 can be complicated by acute respiratory disease syndrome (ARDS), sepsis and septic shock, multiorgan failure, including acute kidney injury and cardiac injury. The mortality rate of COVID 19 is still increasing in other countries than China now. At present, there is limited evidence from randomized clinical trials to support any vaccines or pharmacological treatments from conventional medicine for COVID-19. (2) According to Siddha system of medicine, the symptoms and signs of COVID 19 are identified as the aggravation of Iyam and which later associated with other Uyir thathukkal Vali and Azhal and expressed as Thontham (Mukkutram) leads to Sanni. (3) Siddha medicine has played a major role in controlling the mortality rate of chikungunya and dengue in Tamil Nadu by administration of Nilavembu Kudineer during 2015. (4) Siddha medicine has contributed in lowering health burden during public health emergency. Siddha Medicine has a good potential to combat COVID-19. (5) Nilavembu Kudineer (NVK) is one of the standard medicines which are used as anti-viral Siddha drug especially against Chikungunya and Dengue for the past epidemic outbreaks. It can be also used as a Prophylactic drug by Siddha Physicians in South Indian region. Recent in-vitro Studies in NVK revealed that ethanoic extract of NVK is having anti-viral properties against Chikungunya and Dengue (6). Moreover, Toxicity studies of NVK also found to be safety for consumption (7). Apart from this, anti-pyretic, anti-microbial, and anti-inflammatory and Immuno Stimulant activities of NVK also proven by a Phyto-chemical Screening Studies (8), (9). Recent Clinical studies revealed the Prophylactic and anti-viral activities of NVK in Viral Fevers (10). So we can take NVK as a comparator for control group along with Standard Allopathy regimen. In this context, one of the classical formulations from Siddha system of medicine is Kabasura Kudineer (KSK) consists of 15 herbals ingredients which individually has anti-viral activity (11). Cucurbitacin B (-112.09), Cardiofoliolide (-111.5), Apigenin (-98.84) and Pyrethrin (-92.98) presented in the KSK were found to be effective in preventing novel corona virus binding and replication. (12) In Silico studies of KSK has been proved potent ingredients against SARS COV-2 Spike proteins (13). Determination of organoleptic characters, preliminary phyto-chemical analysis, physico-chemical analysis, TLC photo documentation and HPTLC fingerprint studies on KSK were analysed. (14) Toxicological study on KSK showed that it is safe (15). KSK also possess anti-pyretic, anti-inflammatory and anti-bacterial effect. So we can take KSK as a trial drug for study group along with Standard Allopathy regimen. However, in the absence of systematic evaluation of the potential of integrated therapy (with Standard of care and KSK&amp; NVK) from Siddha system of medicine in COVID 19, we propose as a comparative study.</td>
</tr>
</tbody>
</table>