



Clinical Trial Details (PDF Generation Date :- Sat, 03 Jun 2023 08:54:31 GMT)

<b>CTRI Number</b>	CTRI/2020/05/025370 [Registered on: 27/05/2020] - <b>Trial Registered Prospectively</b>	
<b>Last Modified On</b>	25/05/2020	
<b>Post Graduate Thesis</b>	No	
<b>Type of Trial</b>	Interventional	
<b>Type of Study</b>	Ayurveda	
<b>Study Design</b>	Single Arm Study	
<b>Public Title of Study</b>	Evaluation of Role of Ayurvedic Drug- Guduchi Ghan Vati in the treatment of COVID-19 related illness	
<b>Scientific Title of Study</b>	Evaluation of Efficacy and Safety of Ayurveda Intervention (Guduchi Ghan Vati) in the management of COVID-19 infection (Asymptomatic & Mild symptoms)- An open label single arm prospective clinical trial.	
<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>	Prof Dr Abhimanyu Kumar
	<b>Designation</b>	Vice Chancellor
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<b>Details Contact Person (Scientific Query)</b>	<b>Details Contact Person (Scientific Query)</b>	
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<b>Details Contact Person (Public Query)</b>	<b>Details Contact Person (Public Query)</b>	
	<b>Name</b>	DR SANJAY SRIVASTAVA
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<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>			
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<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
<b>Name</b>	Dr SR Rajasthan Ayurved University Jodhpur			
<b>Address</b>	Dr. S.R. Rajasthan Ayurved University, Jodhpur, Nagaur Road, Kadwad, Jodhpur 342037			
<b>Type of Sponsor</b>	Government funding agency			
<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>
	Prof Dr ABHIMANYU KUMAR	Covid care centre	Boranada Jodhpur Jodhpur RAJASTHAN	8800543828 vc.dsrrau@gmail.com
	Prof Dr ABHIMANYU KUMAR	Covid care centre- University Hospital	University Hospital DSRRAU Jodhpur Jodhpur RAJASTHAN	8800543828 vc.dsrrau@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>
	IEC UCA DSRRAU Jodhpur	Approved	18/05/2020	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>	
	Patients		Coronavirus as the cause of diseases classified elsewhere	
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>	
	Intervention	Guduchi Ghan Vati	Dose: 500mg- BD(Twice a day), Route of Administration- Oral, Duration- 30 days	
	Comparator Agent	Not applicable	Not applicable	
<b>Inclusion Criteria</b>	<b>Inclusion Criteria</b>			
	<b>Age From</b>	18.00 Year(s)		
	<b>Age To</b>	60.00 Year(s)		
	<b>Gender</b>	Both		
	<b>Details</b>	1. All hospitalized cases above 18-60 years of age, clinically diagnosed with corona virus disease 2019 (Covid19) and who are asymptomatic or having Mild symptoms.  2. Participants who can take medicines orally.   3. Patients willing to provide signed informed consent. 		
<b>Exclusion Criteria</b>	<b>Exclusion Criteria</b>			
	<b>Details</b>	1. Cases of severe vomiting which would affect oral administration of		



	<p>medicine difficult.</p> <ol style="list-style-type: none"> <li>2. Cases of respiratory failure and requiring mechanical ventilation.</li> <li>3. Patients having Alanine Transaminase (ALT) or Aspartate Transaminase (AST) &gt; 5 times the upper range of normal limits.</li> <li>4. Patients with COVID-19 in critical condition or ARDS or NIAD 8 –point ordinal score-2 (Hospitalized, on invasive mechanical Ventilation or extra corporeal membrane oxygenation</li> <li>5. Combined organ failure requiring ICU monitoring.</li> <li>6. Patients with uncontrolled Diabetes Mellitus, (HbA1c more than 8.0), Malignant Hypertension (systolic BP more than 180 and diastolic 110), Chronic Renal Failure and those on immunosuppressive medication.</li> <li>7. Patients with history of malignancy, IHD, CAD, triple vessel disease, history of CABG, Stroke, etc.</li> <li>8. Any other condition, which as per the investigator would jeopardize the outcome of the trial.</li> </ol>				
<b>Method of Generating Random Sequence</b>	Adaptive randomization, such as minimization				
<b>Method of Concealment</b>	Not Applicable				
<b>Blinding/Masking</b>	Open Label				
<b>Primary Outcome</b>	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td>1. Clinical cure rate: Time to get a negative status of Covid-19. (defined as viral load of respiratory specimen negative for two consecutive times when tested in an interval of two days) [Time frame 1 month]</td> <td>[Time frame 1 month]</td> </tr> </tbody> </table>	Outcome	Timepoints	1. Clinical cure rate: Time to get a negative status of Covid-19. (defined as viral load of respiratory specimen negative for two consecutive times when tested in an interval of two days) [Time frame 1 month]	[Time frame 1 month]
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<b>Secondary Outcome</b>	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td> <ol style="list-style-type: none"> <li>1.Duration of fever and each of the respiratory symptoms</li> <li>2.Improvement in hematological and laboratory parameters (lymphocyte count, Hs-CRP, ESR, TC,DC, Absolute lymphocyte count, LFT,RFT,IL-6, Ig E, Ig-G,Ig-M, LDH, Platelet count),</li> <li>3.No of cases Reporting any ADR/AE</li> <li>4.Number of patients referred.</li> <li>5.Number of cases that required invasive or non-invasive oxygen therapy during the intervention.</li> <li>6.Number of cases that progressed to multi-organ failure while under clinical trial.</li> </ol> </td> <td>[Time Frame: 1 month]</td> </tr> </tbody> </table>	Outcome	Timepoints	<ol style="list-style-type: none"> <li>1.Duration of fever and each of the respiratory symptoms</li> <li>2.Improvement in hematological and laboratory parameters (lymphocyte count, Hs-CRP, ESR, TC,DC, Absolute lymphocyte count, LFT,RFT,IL-6, Ig E, Ig-G,Ig-M, LDH, Platelet count),</li> <li>3.No of cases Reporting any ADR/AE</li> <li>4.Number of patients referred.</li> <li>5.Number of cases that required invasive or non-invasive oxygen therapy during the intervention.</li> <li>6.Number of cases that progressed to multi-organ failure while under clinical trial.</li> </ol>	[Time Frame: 1 month]
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<b>Target Sample Size</b>	<p><b>Total Sample Size=40</b>  <b>Sample Size from India=40</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></p>				
<b>Phase of Trial</b>	N/A				
<b>Date of First Enrollment (India)</b>	04/06/2020				
<b>Date of First Enrollment (Global)</b>	No Date Specified				
<b>Estimated Duration of Trial</b>	<p><b>Years=0</b>  <b>Months=1</b>  <b>Days=15</b></p>				
<b>Recruitment Status of Trial (Global)</b>	Not Applicable				



<b>Recruitment Status of Trial (India)</b>	Not Yet Recruiting
<b>Publication Details</b>	NIL
<b>Brief Summary</b>	<p>1. To assess the efficacy of Guduchi Ghan Vati in the patients of positive coronavirus Disease. (Laboratory confirmation + Patients with/ without uncomplicated respiratory tract infection which may have non-specific symptoms such as fever, fatigue, cough, anorexia, malaise, muscle pain, sore throat, dyspnoea, nasal congestion, or headache).</p> <p>2.To assess the clinical safety of Guduchi Ghan Vati in the patients of positive coronavirus Disease.</p>