Clinical Trial Details (PDF Generation Date :- Fri, 14 Aug 2020 10:11:20 GMT)

CTRI Number	CTRI/2020/05/025370 [Registered on: 27/05/2020] - **Trial Registered Prospectively**
Last Modified On	25/05/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Ayurveda
Study Design	Single Arm Trial
Public Title of Study	Evaluation of Role of Ayurvedic Drug- Guduchi Ghan Vati in the treatment of COVID-19 related illness
Scientific Title of Study	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.

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	Prof Dr Abhimanyu Kumar
Designation	Vice Chancellor
Affiliation	Dr. S.R. Rajasthan Ayurved University, Jodhpur
Address	Office of the Vice Chancellor, Room no- 101, Dr. S.R. Rajasthan Ayurved University, Jodhpur, Nagaur Road, Kadwad, Jodhpur Jodhpur RAJASTHAN 342037 India
Phone	8800543828
Fax	
Email	vc.dsrrau@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Prof Dr Abhimanyu Kumar
Designation	Vice Chancellor
Affiliation	Dr. S.R. Rajasthan Ayurved University, Jodhpur
Address	Office of the Vice Chancellor, Room no- 101, Dr. S.R. Rajasthan Ayurved University, Jodhpur, Nagaur Road, Kadwad, Jodhpur Jodhpur RAJASTHAN 342037 India
Phone	8800543828
Fax	
Email	vc.dsrrau@gmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	DR SANJAY SRIVASTAVA
Designation	Assistant professor
Affiliation	Dr. S.R. Rajasthan Ayurved University, Jodhpur
Address	Department of Shalya Tantra, University College of Ayurveda, Room Number 162, Dr. S.R. Rajasthan Ayurved University, Jodhpur, Nagaur Road, Kadwad, Jodhpur Jodhpur RAJASTHAN 342037

	India
Phone	9414410383
Fax	
Email	sanjayphyayu@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Dr. S.R. Rajasthan Ayurved University, Jodhpur, Nagaur Road, Kadwad, Jodhpur 342037

Primary Sponsor

Primary Sponsor Details	
Name	Dr SR Rajasthan Ayurved University Jodhpur
Address	Dr. S.R. Rajasthan Ayurved University, Jodhpur, Nagaur Road, Kadwad, Jodhpur 342037
Type of Sponsor	Government funding agency

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 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

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
IEC UCA DSRRAU Jodhpur	Approved	18/05/2020	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	Guduchi Ghan Vati	Dose: 500mg- BD(Twice a day), Route of Administration- Oral, Duration- 30 days
Comparator Agent	Not applicable	Not applicable

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	60.00 Year(s)
Gender	Both
Details	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.

Exclusion Criteria

Exclusion Criteria

Details	1. Cases of severe vomiting which would affect oral administration of medicine difficult. 2. Cases of respiratory failure and requiring mechanical ventilation. 3. Patients having Alanine Transaminase (ALT) or Aspartate Transaminase (AST) > 5 times the upper range of normal limits. 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 5. Combined organ failure requiring ICU monitoring. 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. 7. Patients with history of malignancy, IHD, CAD, triple vessel disease, history of CABG, Stroke, etc. 8. Any other condition, which as per the investigator would jeopardize the outcome of the trial.

Method of Generating Random Sequence	Adaptive randomization, such as minimization
Method of Concealment	Not Applicable
Blinding/Masking	Open Label

Primary Outcome

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]

Secondary Outcome

Outcome	Timepoints
1.Duration of fever and each of the respiratory symptoms 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), 3.No of cases Reporting any ADR/AE 4.Number of patients referred. 5.Number of cases that required invasive or non-invasive oxygen therapy during the intervention. 6.Number of cases that progressed to multi-organ failure while under clinical trial.	[Time Frame: 1 month]

Target Sample Size	**Total Sample Size=**40 **Sample Size from India=**40 **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	N/A
Date of First Enrollment (India)	04/06/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**1 **Days=**15
Recruitment Status of	Not Applicable

Trial (Global)	
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	NIL
Brief Summary	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). 2.To assess the clinical safety of Guduchi Ghan Vati in the patients of positive coronavirus Disease.