Clinical Trial Details (PDF Generation Date :- Wed, 07 Jun 2023 17:22:16 GMT)

CTRI Number	CTRI/2020/09/028044 [Registered on: 24/09/2020] - **Trial Registered Prospectively**
Last Modified On	02/10/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Ayurveda
Study Design	Randomized, Parallel Group Trial
Public Title of Study	Phase IV study to evaluate the safety and efficacy of Artemisinin- a herbal supplement on COVID-19 subjects
Scientific Title of Study	A Prospective, Randomized, Multi-center, Open label, Interventional Study to Evaluate the Safety and Efficacy of Artemisinin 500 mg capsule in Treatment of Adult Subjects with COVID-19

Secondary IDs if Any

Secondary ID	Identifier
ARTI/WBPL/P4/2020/01 Version 1.1 dated 25 Aug 2020	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	
Designation	
Affiliation	
Address	
Phone	
Fax	
Email	

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Antaryami Maharana
Designation	Head-Medical Affairs
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Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Mukesh Kumar
Designation	Manager- Regulatory Department
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Source of Monetary or Material Support

Source of Monetary or Material Support
> Windlas Biotech Private Limited Khasra no. 141 to 143 &145,Mohabewala, Industrial Area, Dehradun, 248110 Uttarakhand India

Primary Sponsor

Primary Sponsor Details	
Name	Windlas Biotech Private Limited
Address	Plant 2,Khasra no. 141 to 143 &145,Mohabewala, Industrial Area, Dehradun, 248110 Uttarakhand India
Type of Sponsor	Pharmaceutical industry-Indian

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
Dr K Sunil Naik	Government Medical College & Government General Hospital, Srikakulam	Department of General Medicine, Room No 4, Ground Floor, OPD Block,Government Medical College & Government General Hospital, Srikakulam-532001 Srikakulam ANDHRA PRADESH	8942279033 rimsresearch@gmail.com
Dr Vijay B Barge	Rajarshi Chhatrapati Shahu Maharaj Government Medical college and Chhatrapati Pramila Raje Hospital	Department of Medicine, CPR Hospital Campus, Dasara Chowk,Kolhapur-431001 Kolhapur MAHARASHTRA	9011066766 vijaybarge6766@gmail.com
Dr Prashant V Rahate	Seven Star Hospital	Department of Surgery, O.P.D. No.: 1, Jagnade Square, KDK College Road,Nagpur-440009 Nagpur MAHARASHTRA	09822464068 prashantrahate84@yahoo.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee,Government Medical College and Government General Hospital, Srikakulam	Approved	28/09/2020	No
Institutional Ethics Committee,Rahate Surgical Hospital, Nagpur	Approved	05/09/2020	No
Institutional Ethics Committee,RCSMGMC and CPR Hospital , Kolhapur	Approved	09/09/2020	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	Artemisinin 500 mg capsule	The dose regimen will be in cycles. In a cycle a subject will receive Artemisinin 500 mg capsule once daily plus SOC on Day 1 to Day 5 followed by 5 days off (no dosing of Artemisinin) or SOC alone. A subject can have a total of consecutive 3 cycles maximum. Here SOC is Standard of Care as per CLINICAL MANAGEMENT PROTOCOL: COVID-19, Government of India Ministry of Health and Family Welfare Directorate General of Health Services (EMR Division)
Comparator Agent	SOC	Standard of Care as per CLINICAL MANAGEMENT PROTOCOL: COVID-19, Government of India Ministry of Health and Family Welfare Directorate General of Health Services (EMR Division)

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	60.00 Year(s)
Gender	Both
Details	1.Male or female subjects of ?18 to 60 years of age both inclusive 2.Subjects willing to give informed consent and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures 3.Confirmed case of COVID-19 infection by RT-PCR and mild and moderate (without oxygen therapy or assisted ventilation) cases of COVID-19. Scores of 2-4 on the WHO Clinical Progression Scale 4.Time interval between symptoms onset and randomization of no more than 7 days 5.One or more of the following symptoms: Fever Cough Sore throat Headache Nasal congestion Malaise Diarrhea Loss of smell Loss of taste 6.Male and female subjects of childbearing potential must agree to use a highly effective method of contraception throughout the study and for at least 30 days after the last dose of assigned treatment. A subject is of childbearing potential if, in the opinion of the investigator, he/she is biologically capable of having children and is sexually active.

Exclusion Criteria

Exclusion Criteria	
Details	1. Subjects with history of severe infections (pneumonia, septicemia, etc.), severe cardiac or pulmonary diseases, or received immunosuppressive therapy or other investigational drugs within the previous 30 days of screening 2. Known or suspected hypersensitivity to Artemisinin

	3. Women of child bearing potential who are currently pregnant, lactating or who are not willing to use contraception during the entire duration of the study 4. Men who are unwilling to use contraception while receiving investigational product 5. Subjects with history of severe disease other than COVID-19 which is expected to prevent compliance with the present protocol 6. Subjects with history of severe renal and hepatic impairment. (creatine ?2 mg/dl; liver enzymes and bilirubin 2.5 times ULN; alkaline phosphatase 1.5 times ULN) 7. Recent treatment with Artemisinin or Artemisinin based antimalarials in the past 7 days 8. Known history of failure to control systemic fungal, bacterial or viral infection 9. Patients with the history of following co-morbidities: diabetes, hypertension with or without cardiac symptoms, morbid obesity with diabetes and/or hypertension or any other metabolic syndrome 10. Subjects with known human immunodeficiency virus (HIV) or hepatitis B or C classes of active viral infection 11. Have a history of neurological or psychiatric disorders, including epilepsy or dementia 12. Subjects for whom ventilator support is required at screening 13. Patients not willing to stay in hospital for 5 days of isolation following diagnosis of Covid-19 14. Subjects not willing to give their informed consent to participate in the clinical trial 15. According to the investigator judgment there are concomitant diseases with a serious safety hazard or affect the subject 16. Using other experimental drugs or participating in other clinical trials in the prior one month
Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Centralized
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
Safety Assessments - Adverse events (AEs) during the study - Serious adverse events (SAEs) during the study	Day 28

Secondary Outcome

Outcome	Timepoints
Efficacy -Relief in the sign and symptoms of COVID-19 as per WHO Clinical Progression Scale. -Relief in the sign and symptoms of COVID-19 per the Duration of Symptoms.	Day 28

Target Sample Size	**Total Sample Size=**120 **Sample Size from India=**120 **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	Phase 4
Date of First Enrollment (India)	30/09/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**7

	Days=0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	NIL
Brief Summary	This will be an open label, prospective, multi-center, comparative, interventional study to evaluate safety and efficacy of Artemisinin 500 mg in subjects with mild to moderate COVID-19. Initially subjects having mild to moderate COVID-19 will be screened as per predefined eligibility criteria for the study. Eligible 120 subjects will be enrolled to receive treatment with Artemisinin and SOC (Standard of Care as per CLINICAL MANAGEMENT PROTOCOL: COVID-19, Government of India Ministry of Health and Family Welfare Directorate General of Health Services (EMR Division)) or SOC. Subjects will be randomized in 2:1 ratio. Group 1 will have 80 subjects and Group 2 will have 40 subjects.