Clinical Trial Details (PDF Generation Date :- Sat, 30 Sep 2023 11:47:56 GMT)

CTRI Number	CTRI/2020/05/025224 [Registered on: 18/05/2020] - **Trial Registered Prospectively**
Last Modified On	16/05/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group Trial
Public Title of Study	Study to efficacy of Ivermectin in patients of COVID-19
Scientific Title of Study	Interventional study to assess the efficacy of Ivermectin with standard of care treatment versus standard of care in patients of COVID-19 at R D Gardi Medical College, Ujjain, India

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	Dr Sunil Rathi
Designation	Professor
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
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Details Contact Person (Public Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
> R D Gardi Medical College Agar Road, Surasa, Ujjain Madhya Pradesh 456006 India

Primary Sponsor

Primary Sponsor Details	
Name	R D Gardi Medical College
Address	Agar Road, Surasa, Ujjain Madhya Pradesh 456006 India
Type of Sponsor	Private medical college

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 Ashish Pathak	R D Gardi Medical College, Ujjain	3rd Floor, Department of Pediatrics C R Gardi Hospital R D Gardi medical College Ujjain MADHYA PRADESH	9302239899 drashish.jpathak@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee, R D Gardi Medical College, Ujjain	Approved	13/05/2020	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	Ivermectin	Ivermectin 12mg OD at night Route of administration- Oral Duration of therapy - 2 days with standard of care as per hospital guidelines
Comparator Agent	Standard of care	Standard of care as per hospital guidelines.

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	75.00 Year(s)
Gender	Both
Details	1. Adults (age ?18 years to ?75 years) 2. Laboratory-confirmed SARS-CoV-2 infection and, in the view of the responsible doctor, no contra-indication to any of the study treatments 3. Hospitalized at R D Gardi Medical College, Ujjain Madhya Pradesh

Exclusion Criteria

Exclusion Criteria	
Details	1. Anticipated transfer to another hospital, within 72 hours, which is not a study site 2. Known allergy to study medication or its components (non-medicinal ingredients) 3. Known HIV infection

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	An Open list of random numbers
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
Effect of Ivermectin on eradication of virus. Test for virus at 1, 3 and 5 days from beginning of trial drug started for the patient in the hospital	3 months

Secondary Outcome

Outcome	Timepoints
1. Overall safety of the study drug 2. Duration of hospitalization 3. Improvement in the abnormal laboratory values	3 months

Target Sample Size	**Total Sample Size=**50 **Sample Size from India=**50 **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 2
Date of First Enrollment (India)	24/05/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**6 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	Results will be published in relevant open access peer-reviewed scientific journals.
Brief Summary	The aim of this study is to validate the antivirus effectiveness of Ivermectin on coronavirus i.e COVID 19 and study its effectiveness in combating COVID 19 pandemics. At present, there are no specific treatments for COVID-19. Ivermectin, an FDA-approved anti-parasitic previously shown to have broad-spectrum anti-viral activity in vitro, is an inhibitor of the causative virus (SARS-CoV-2), with a single addition to Vero-hSLAM cells 2 hours post infection with SARSCoV-2 able to affect about 5000-fold reduction in viral RNA at 48 h. Ivermectin is a CDSCO approved drug. However, it requires further investigation for possible benefits COVID-19 patients and further eradication of COVID-19 virus.