



Clinical Trial Details (PDF Generation Date :- Wed, 28 Jul 2021 10:20:44 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)
Name		Dr Ashish Pathak
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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	<p>The aim of this study is to validate the antiviral effectiveness of Ivermectin on coronavirus i.e COVID 19 and study its effectiveness in combating COVID 19 pandemics.</p> <p>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.</p>	