Clinical Trial Details (PDF Generation Date :- Sat, 30 Sep 2023 11:17:48 GMT)

CTRI Number	CTRI/2020/08/027225 [Registered on: 18/08/2020] - **Trial Registered Prospectively**
Last Modified On	05/01/2021
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	Ivermectin as a possible treatment for COVID-19
Scientific Title of Study	Ivermectin as a potential treatment for COVID 19: A double blind randomized placebo-controlled 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	Ravi Kirti
Designation	Additional Professor
Affiliation	All India Institute of Medical Sciences
Address	Department of General Medicine, 1st Floor, OPD Building, AIIMS, Phulwari Sharif, Patna Patna BIHAR 801507 India
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Email	drravikirti@aiimspatna.org

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Ravi Kirti
Designation	Additional Professor
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Source of Monetary or Material Support

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> All India Institute of Medical Sciences, Phulwari Sharif, Patna 801507

Primary Sponsor

Primary Sponsor Details	
Name	AIIMS Patna
Address	Phulwari Sharif Patna 801503
Type of Sponsor	Research institution and hospital

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
Ravikirti	AII India Institute of Medical Sciences, Patna	COVID Wards, IPD Building, AIIMS Phulwari Sharif Patna 801507 Patna BIHAR	9572424447 drravikirti@aiimspatna.org

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
AIIMS, Patna	Approved	11/08/2020	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	12 mg orally to be administered once daily on days 1 and 2
Comparator Agent	Placebo tablets	A placebo tablet similar to Ivermectin 12 mg (provided by the manufacturer) to be given once daily on days 1 and 2.

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	Patients admitted with COVID-19 with mild to moderate severity

Exclusion Criteria

Exclusion Criteria	
Details	History of allergy to Ivermectin Unwillingness to participate in the study

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Centralized
Blinding/Masking	Participant, Investigator, Outcome Assessor and Date-entry Operator Blinded

Primary Outcome

Outcome	Timepoints
Negative RT-PCR	Day 6

Secondary Outcome

Outcome	Timepoints
In-hospital mortality	NA
ICU Admission	NA
Mechanical Ventilation	NA
Discharge by day 10	Day 10

Target Sample Size	**Total Sample Size=**90 **Sample Size from India=**90 **Final Enrollment numbers achieved (Total)=**115 **Final Enrollment numbers achieved (India)=**115
Phase of Trial	N/A
Date of First Enrollment (India)	28/08/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**4 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	NIL
Brief Summary	Ivermectin is a widely used and safe anti-parasitic drug. It has been reported to have an in-vitro activity against SARS-CoV-2. However, no randomized controlled trial has been done yet to study the efficacy of this drug in COVID-19. The proposed study is a single center study to assess the efficacy of the drug in COVID-19 cases with mild to moderate severity as defined by the Ministry of Health and Family Welfare, Government of India. _____