Clinical Trial Details (PDF Generation Date :- Sat, 03 Jun 2023 09:49:54 GMT)

CTRI Number	CTRI/2020/08/027394 [Registered on: 26/08/2020] - **Trial Registered Prospectively**
Last Modified On	05/07/2021
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group Trial
Public Title of Study	Assessment of response of ivermectin on virological clearance in COVID 19 patients
Scientific Title of Study	Assessment of response of ivermectin on virological clearance in COVID 19: single centre, open labelled, randomised 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	ROMIT SAXENA
Designation	Assistant Professor
Affiliation	Maulana Azad Medical College
Address	Maulana Azad Medical College, Bahadur Shah Zafar Road Bahadur Shah Zafar Marg, New Delhi-110002 Central DELHI 110002 India
Phone	
Fax	
Email	drromit@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	ROMIT SAXENA
Designation	Assistant Professor
Affiliation	Department of Pediatrics, Maulana Azad Medical College
Address	Department of Pediatrics, Maulana Azad Medical College, Bahadur Shah Zafar Road , New Delhi Bahadur Shah Zafar Marg, New Delhi-110002 Central DELHI 110002 India
Phone	
Fax	
Email	drromit@gmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	ROMIT SAXENA
Designation	Assistant Professor
Affiliation	Department of Pediatrics, Maulana Azad Medical College
Address	Department of Pediatrics, Maulana Azad Medical College, Bahadur Shah Zafar Road , New Delhi Bahadur Shah Zafar Marg, New Delhi-110002 Central DELHI 110002 India

Phone	
Fax	
Email	drromit@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> no monetary support for the study. Study is being conducted at Department of Pediatrics, Maulana Azad Medical college and associated Lok Nayak Hospital

Primary Sponsor

Primary Sponsor Details	
Name	not applicable
Address	not applicable
Type of Sponsor	Other [not applicable]

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 Romit Saxena	maulana azad medical college and associated LN hospital	Department of Pediatrics, Maulana Azad Medical College and associated Lok Nayak Hospital, Bahadur Shah Zafar Marg, New Delhi-110002 Central DELHI	9597650364 drromit@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
institutional ethics committee, Maulana Azad medical college	Approved	19/08/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Certain infectious and parasitic diseases

Intervention / Comparator Agent

Type	Name	Details
Intervention	administration of drug ivermectin for patients of mild or moderate COVID and assess response on virological clearance	administration of drug ivermectin for patients of mild or moderate COVID and assess response on virological clearance . The drug will be administered as a single dose at dose of 0.2 mg/kg as per institutional protocols. It will not be repeated.
Comparator Agent	no ivermectin administration , rest all patients, will receive treatment as per departmental protocol, which may include, vitamin C, Zinc, antipyretic, ranitidine/omeprazole/chloroquine , azithromycin etc. The only	no ivermectin administration , rest all patients, will receive treatment as per departmental protocol, which may include, vitamin C, Zinc, antipyretic, ranitidine/omeprazole/chloroquine , azithromycin etc. The only

	exception is the use of ivermectin, which will be used in the study group and not in the control group	exception is the use of ivermectin, which will be used in the study group and not in the control group

Inclusion Criteria

Inclusion Criteria	
Age From	5.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1.Patients admitted with COVID 19 , positive report, or are detected as positive after admission 2. Present within 5 days of symptom onset 3.The patient must be between the ages >5 years and 15 Kg, until 65 years of age 4.Women in child bearing age(14-50 years) within 14 days of LMP only 5.Mild-moderate symptoms at presentation as per Ministry of Family welfare, Government of India definitions

Exclusion Criteria

Exclusion Criteria	
Details	1. Known history of ivermectin allergy 2. Hypersensitivity to any component of ivermectin 3. Refusal of consent (Appendix 5 and 6). 4. Co-morbidities e.g. Acute or chronic renal disease , History of coronary disease , pregnancy, History of cerebrovascular disease and malignancy 5. Current use of CYP 3A4 or P-gp inhibitor drugs such as quinidine, amiodarone, diltiazem, spironolactone, verapamil, clarithromycin, erythromycin, itraconazole, ketoconazole, cyclosporine, tacrolimus, indinavir, ritonavir or cobicistat. Concomitant use of critical CYP3A4 substrate drugs such as warfarin. 6.Prior use of ivermectin in last 15 days

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Sequentially numbered, sealed, opaque envelopes
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
PRIMARY OBJECTIVE To assess the Efficacy of single dose of Ivermectin, given within first 5 days of symptom onset, as assessed by RT PCR for SARS CoV 2, at 3rd and 7th day after start of treatment	At Admission, 3rd and 7th Day after start of treatment

Secondary Outcome

Outcome	Timepoints
Viral load as determined by PCR cycle threshold on Day 3 and Day 7(since ivermectin administration).	DAy 0, Day 3 and Day 7
Symptom resolution as assessed everyday till 7 days of admission and progression across clinical staging	Everyday for 1st 7 days
Telephonic conversation at 21 day from day of administration of drug, to assess any residual symptoms.	21st day after administration of dose
Assess the safety profile of the drug	Everyday for 1st 7 days

Target Sample Size

Total Sample Size=56
Sample Size from India=56
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)	02/09/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**3 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Closed to Recruitment of Participants
Publication Details	publication after study is completed
Brief Summary	On Dec 31, 2019, WHO was informed of a cluster of unexplained cases of pneumonia in Wuhan, Hubei province, China (1,2,3,4). The World Health Organization (WHO) has described this disease process, called as COVID-19 (Coronavirus disease-2019). There is an urgency of developing a therapeutic strategy in order to control the spread of COVID-19(5). Ivermectin is FDA approved drug, known to have wide-spectrum antiviral activity against number of viruses under in vitro conditions (5,6,7,8,9). The drug has an excellent safety profile, and has been used for more than 30 years with an excellent safety profile. More than 2.7 billion doses have been distributed both as individual treatment and as control of neglected tropical diseases (NTDs) at the approved dose of 150–200 ?g/kg, yearly, and with no major safety concerns(10,11). This drug has demonstrated in vitro efficacy against COVID 19 and there are clinical trials that have been initiated, to assess the efficacy in COVID 19. The drugs have been approved by LNJP institutional committee for use in all admitted COVID 19 patients, with precautions in specific groups. We are already using the drug, in admitted patients, in department of pediatrics (12). Given the fact that it is an easily and locally available, is a cheap drug, with a well-established safety profile, and has demonstrated in-vitro effects against COVID 19, we chose this drug for its potential against COVID 19. For the purpose of this study, we intend to do a single centre, randomized controlled, open labelled trial, to assess, the efficacy of single dose ivermectin, given within first 72 hours, of symptom onset, as assessed by *Reverse transcription polymerase chain reaction* (*RT-PCR)* for severe acute respiratory syndrome coronavirus 2 (SARS CoV 2), at 3rd and 7th day of treatment. We also want to assess through the study, the safety profile of the drug, symptom resolution as assessed everyday till 7 days of admission. At Day 21, from the administration of drug. we intend to have a telephonic conversation to assess any residual symptoms. For the purpose of the study, we shall include patients, who satisfy the inclusion and exclusion criterion as detailed further in this document, then randomize them into either ivermectin or control group, before administering single dose of ivermectin. Through this study, the patient data generated, will be entered into a predesigned proforma, and patient confidentiality shall be strictly maintained. **Bibliography** 1. Chan JF-W, Yuan S, Kok K-H, To KK-W, Chu H, Yang J, et al. A familial cluster of pneumonia associated with the 2019 novel coronavirus indicating person-to-person transmission: a study of a family cluster. The Lancet. 2020 Feb 15;395(10223):514–23. 2. Zhu N, Zhang D, Wang W, Li X, Yang B, Song J, et al. A Novel Coronavirus from Patients with Pneumonia in China, 2019. New England Journal of Medicine. 2020 Feb 20;382(8):727–33. 3. Chu H, Chan JF-W, Yuen TT-T, Shuai H, Yuan S, Wang Y, et al. Comparative tropism, replication kinetics, and cell damage profiling of SARS-CoV-2 and SARS-CoV with implications for clinical manifestations, transmissibility, and laboratory studies of COVID-19: an observational study. The Lancet Microbe. 2020 May; 1(1):e14–23. 4. Zhou P, Yang X-L, Wang X-G, Hu B, Zhang L, Zhang W, et al. A pneumonia outbreak associated with a new coronavirus of probable bat origin. Nature. 2020 Mar;579(7798):270–3. 5. Choudhary R, Sharma AK. Potential use of hydroxychloroquine, ivermectin and azithromycin drugs in fighting COVID-19: trends, scope and relevance. New Microbes New Infect. 2020 May; 35:100684.

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