Clinical Trial Details (PDF Generation Date :- Fri, 16 Apr 2021 19:32:29 GMT)

CTRI Number	CTRI/2020/08/027282 [Registered on: 20/08/2020] - **Trial Registered Prospectively**
Last Modified On	19/08/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Multiple Arm Trial
Public Title of Study	Prophylactic Ivermectin in COVID 19 Contacts
Scientific Title of Study	Effectiveness of Ivermectin in preventing development of symptomatic Covid-19 among primary contacts of newly diagnosed Covid-19 positive patients at a tertiary care hospital in North India - an interventional study

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 Rambha Pathak
Designation	Dean Prof. and head
Affiliation	Govt Institute of Medical Sciences
Address	Room no. 135 Deans office Government Institute of Medical Sciences Greater Noida UP Gautam Buddha Nagar UTTAR PRADESH 201312 India
Phone	8826843180
Fax	
Email	rambha_p@yahoo.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Saurabh Srivastava
Designation	Prof. & Head, Dept. of Medicine
Affiliation	Govt Institute of Medical Sciences
Address	Room No.101 Department of Medicine Government Institute of Medical Sciences Greater Noida UP Gautam Buddha Nagar UTTAR PRADESH 201312 India
Phone	
Fax	
Email	saurabhsrivas@gmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Hariom Kumar Solanki
Designation	Assistant Professor
Affiliation	Govt Institute of Medical Sciences
Address	Room no. 401 Department of Community Medicine Government Institute of Medical Sciences Greater Noida UP Gautam Buddha Nagar UTTAR PRADESH 201312 India

Phone	
Fax	
Email	hariom.mamc@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Director Government Institute of Medical Sciences Greater Noida Gautam Budh Nagar Uttar Pradesh 201310

Primary Sponsor

Primary Sponsor Details	
Name	Department of Community Medicine
Address	Govt. Institute of Medical Sciences Greater Noida Gautam Budh Nagar Uttar Pradesh
Type of Sponsor	Government medical college

Details of Secondary Sponsor

Name	Address
Dr Rakesh Gupta	Govt. Institute of Medical Sciences Greater Noida UP

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Rambha Pathak	Government Institute of Medical Sciences	Room no. 135 Dept. of Community Medicine Govt Institute of Medical Sciences Greater Noida UP Gautam Buddha Nagar UTTAR PRADESH	08826843180 rambha_p@yahoo.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
GIMS INSTITUTIONAL ETHICS COMMITTEE	Approved	08/08/2020	Yes

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Healthy contact of COVID 19 Patients

Intervention / Comparator Agent

Type	Name	Details
Intervention	Ivermectin 12mg or Ivermectin 36mg single dose orally once only	The study will have two intervention arms. In the intervention Arm 1: 12mg oral Ivermectin will be given to the close family contacts fulfilling the inclusion- exclusion criteria for this study; of the newly diagnosed Covid-19 patient within 24 hours of diagnosis. The drug will be given orally and once only (under supervision). In the intervention Arm 2: 36 mg oral Ivermectin will be given to the close family contacts fulfilling the inclusion- exclusion criteria for this study; of the newly diagnosed Covid-19 patient within 24 hours of

		diagnosis. The drug will be given orally and once only (under supervision).
Comparator Agent	Two Multivitamin tablets	In the control group - each participant will be given 2 (two) multivitamin tablets (available in the supply at the study institute). These tablets will be given orally, under-supervision and only once.

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	60.00 Year(s)
Gender	Both
Details	All the family members of a newly diagnosed Covid-19 patient who are - living with the patient in the last 2 weeks, aged between 18 years and 60 years of age, asymptomatic on the day of diagnosis of the index case.

Exclusion Criteria

Exclusion Criteria	
Details	The following will be excluded from the study: 1. Pregnant or lactating women 2. Those with any degree of ARI symptoms or fever. 3. Person with known history of severe hypersensitivity reaction to previous exposure to Ivermectin. 4. People with pre-existng severe medical conditions according to the judgement of the investigators

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

Primary Outcome

Outcome	Timepoints
Symptomatic Covid-19 among the study participants	Between 7 and 10 days of Ivermectin intake

Secondary Outcome

Outcome	Timepoints
Adverse effects of Ivermectin experienced by the study participants	On the day of Ivermectin intake and between 7 and 10 days of Ivermectin intake

Target Sample Size	**Total Sample Size=**180 **Sample Size from India=**180 **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 3
Date of First Enrollment (India)	31/08/2020
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	1. ?im?ek Yavuz S, Ünal S. Antiviral treatment of COVID-19. Turk J Med Sci. 2020;50(SI-1):611-619. Published 2020 Apr 21. doi:10.3906/sag-2004-145. 2. Caly L, Druce JD, Catton MG, Jans DA, Wagstaff KM. The FDAapproved drug ivermectin inhibits the replication of SARS-CoV-2 in vitro. Antiviral Res. 2020. https://doi.org/ 10.1016/j.antiviral.2020.104787 3. Patrì A, Fabbrocini G. Hydroxychloroquine and ivermectin: A synergistic combination for COVID-19 chemoprophylaxis and treatment?. J Am Acad Dermatol. 2020;82(6):e221. doi:10.1016/j.jaad.2020.04.017.
Brief Summary	Effective medical prophylaxis can help in curbing the transmission of COVID 19. Ivermectin has been found to be having antiviral properties against SARS-COV-2 virus and trials have been started in various parts of the world to study the effectiveness of Ivermectin as a post exposure prophylaxis of COVID 19. Keeping this in view an attempt is being made in the study to determine the effectiveness of single-dose ivermectin 12mg or 36mg in reducing the probability of contracting the infection from positive household contacts in India.