



Clinical Trial Details (PDF Generation Date :- Sat, 03 Jun 2023 09:07:01 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		
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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-existing 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. Patri 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.