



Clinical Trial Details (PDF Generation Date :- Sat, 30 Sep 2023 12:14:00 GMT)

CTRI Number	CTRI/2020/04/024806 [Registered on: 22/04/2020] - Trial Registered Prospectively	
Last Modified On	20/05/2020	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Drug	
Study Design	Randomized, Parallel Group Trial	
Public Title of Study	Imatinib in COVID-19 infection	
Scientific Title of Study	Efficacy of Imatinib in mild SARS CoV2 infection: A randomized 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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	Designation	Assistant Professor
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Source of Monetary or Material Support	Source of Monetary or Material Support			
	> All India Institute of Medical Sciences			
Primary Sponsor	Primary Sponsor Details			
	Name	All India Institute of Medical Sciences		
	Address	Ansari Nagar, New Delhi		
	Type of Sponsor	Government 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
	Akash Kumar	All India Institute of Medical Sciences	Department of Medical Oncology, 2nd Floor, BRA IRCH, AIIMS South DELHI	9910850134 akashjha08@yahoo.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	AIIMS Ethics Committee	Approved	20/04/2020	No
	AIIMS Institutet Ethics Committee	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	Imatinib - Oral Drug	Imatinib- 600mg per oral once daily (D1-D14)	
	Comparator Agent	supportive care	supportive care	
Inclusion Criteria	Inclusion Criteria			
	Age From	18.00 Year(s)		
	Age To	75.00 Year(s)		
	Gender	Both		
	Details	a) Age -18 years and above (no upper age limit) b) Mildly symptomatic Patients admitted in the AIIMS hospital with a proven diagnosis of COVID 19 infection on RT-PCR, with National Early Warning Score (NEWS score) ?3 		
Exclusion Criteria	Exclusion Criteria			
	Details	a) Abnormal Liver function at baseline, i.e. Serum Bilirubin > 1.5 ULN, ALT and AST > 3 ULN. Upto 5 times in case of chronic liver disease. b) Abnormal renal functions at baseline, i.e.. Serum creatinine > 1.5 ULN c) Prior history of exposure to imatinib		



		d) Any other condition assessed by physicians' team that will lead to difficulty in carrying out the trial. e) Pregnant or breast feeding women. f) Patients unable to swallow oral medicines.
Method of Generating Random Sequence	Computer generated randomization	
Method of Concealment	Centralized	
Blinding/Masking	Open Label	
Primary Outcome		
	Outcome	Timepoints
	1. Proportion of patients with negative viral titre in the intervention arm in comparison with those in standard arm on D-7 2. Proportion of patients with negative viral titre in the intervention arm in comparison with those in standard arm on D-14	d-7 & d-14
Secondary Outcome		
	Outcome	Timepoints
	i) To investigate improvement in symptoms at D-3,D-7, D-10 & D-14 ii) To study duration of hospitalization, mechanical ventilation or death by day 28. iii) Safety analysis as per CTCAE version 5.0	Day -14 and Day-28
	Docking studies for the drug will be done during the course of study.	during the course of whole study
Target Sample Size	Total Sample Size=100 Sample Size from India=100 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)	26/04/2020	
Date of First Enrollment (Global)	No Date Specified	
Estimated Duration of Trial	Years=0 Months=2 Days=0	
Recruitment Status of Trial (Global)	Not Applicable	
Recruitment Status of Trial (India)	Open to Recruitment	
Publication Details		
Brief Summary	<p>COVID -19 is a respiratory illness that has led to a anaemic affecting more that 200 countries in the world. It si caused by SARS-CoV2 virus, which is member of Beta Corona-virus family and has s significant genomic homology to SARS and MERS viruses.</p> <p>Due to sudden advent and rapid spread of infection, no antiviral drug has been found to be effective since onset. In view of requirement of long time period to develop a targeted anti-viral, there is a need of repurposing already available drugs, that have in-vitro anti-viral activity.</p> <p>Imatinib is one such drug which has inhibitory activity in early phases of SARS and MERS corona virus infection, studied in-vitro.</p> <p>We hypothesize that imatinib by inhibiting ABL kinases, can have inhibitory activity in SARSCoV2</p>	



infection.