Clinical Trial Details (PDF Generation Date :- Thu, 22 Oct 2020 19:47:45 GMT)

CTRI Number	CTRI/2020/05/025114 [Registered on: 12/05/2020] - **Trial Registered Prospectively**
Last Modified On	27/07/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group Trial
Public Title of Study	A Clinical Study on Favipiravir Compared to Standard Supportive Care in Patients With Mild to Moderate COVID-19.
Scientific Title of Study	A Randomized, Open-label, multicenter study to evaluate the efficacy and safety of Favipiravir combined with STANDARD supportive care in adult Indian patients with mild to moderate COVID-19

Secondary IDs if Any

Secondary ID	Identifier
GPL/CT/2020/002/III, Version: 3.0, dated: 26 Apr 2020	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	
Designation	
Affiliation	
Address	
Phone	
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Email	

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
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Details Contact Person (Public Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
> Glenmark Pharmaceuticals Ltd.

Primary Sponsor

Primary Sponsor Details	
Name	Glenmark Pharmaceuticals Ltd
Address	Glenmark House, B.D. Sawant Marg, Chakala, Andheri East, Mumbai, State: Maharashtra PIN Code: 400099
Type of Sponsor	Pharmaceutical industry-Indian

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 Atul Jindal	AIIMS	Covid Ward , Ayush Building Gate No.01, Department of Pediatric Medicine, Room No.1111, First Floor ,Medical College Complex, Gate no.05,AIIMS, G.E Road Tatibandh Raipur 492099 Raipur CHHATTISGARH	07712572240 dratuljindal@gmail.com
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Dr Anita Mathews	Fortis Hospital Limited	Level 7, Signature floor, Mulund Goregaon Link Road, Bhandup west Mumbai 400078 Mumbai MAHARASHTRA	09606047050 jojosanish@gmail.com
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Dr Rajesh Gosavi	Government medical college and hospital	COVID Hospital and Critical Care Management, Department of medicine, Research room, Second floor, Hanuman Nagar, Ajni Rd, Medical Square Road, Nagpur- 440003 Nagpur MAHARASHTRA	07122743588 gosavirv@hotmail.com
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Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Committee Jaslok Hospital and Research Center	Approved	19/05/2020	Yes
Ethics Committee, Dr. Balabhai Nanavati Hospital	Approved	03/05/2020	No
Ethics Committee, Breach Candy Medical Research Centre	Approved	23/05/2020	No

HCG Multi Specialty Ethics Committee	Approved	08/05/2020	No
Institutional Ethics Committee for Human Research, Medical College Baroda & SSG Hospital	Approved	22/05/2020	No
Institutional Ethics Committee of Fortis Hospitals Limited	Approved	09/06/2020	No
Institutional Ethics Committee, Departmnet of Pharmacology, Govt Medical College Nagpur	Approved	18/05/2020	No
Institutional Ethics Committee, Government Medical College Aurangabad	Approved	12/05/2020	No
Institutional Ethics Committee, Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute	Approved	02/06/2020	No
Institutional Ethics Committee-AIIMS	Approved	11/05/2020	No
Institutional Human Ethics Committee, GMERS Medical College & General hospital	Approved	19/05/2020	No
Max Healthcare Ethics Committee	Approved	11/05/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	26/04/2020

Health Condition / Problems Studied

Health Type	Condition
Patients	Coronavirus as the cause of diseases classified elsewhere

Intervention / Comparator Agent

Type	Name	Details
Intervention	Favipiravir 200mg Tablets	Dosage Form: Tablets. Dosage Frequency: 3,600 mg (1,800 mg BID) (Day 1) + 1,600 mg (800 mg BID) (Day 2 or later) for up to maximum of 14 days. Mode of Administration: Oral
Comparator Agent	Standard Supportive Care	These patients will be managed by standard supportive care.

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	75.00 Year(s)
Gender	Both
Details	Voluntarily participating in the clinical study; fully understanding and being fully informed of the study and having signed the Informed Consent Form (ICF); willingness and capability to complete all the study procedures.

	Age 18-75 years (inclusive) at the time of signing ICF. Patients with laboratory confirmation of infection with SARS-CoV-2 by positive RT-PCR (within 48 hours prior to randomization). For female subjects: evidence of post-menopause, or, for pre-menopause subjects, negative pretreatment serum or urine pregnancy test. Eligible subjects of child-bearing age (male or female) must agree to take effective contraceptive measures (including hormonal contraception, barrier methods or abstinence) with his/her partner during the study period and for at least 7 days following the last study treatment. Not participating in any other interventional drug clinical studies before completion of the present study. Additional Inclusion criteria for mild cases only: Time interval between symptoms onset and randomization to no more than 7 days. Pyrexia (temperature No more than four of the following of mild severity, and no more than two of moderate severity (Mild is defined as symptoms not requiring any or minimal therapeutic intervention; moderate is defined as symptoms which produce small impairment of function and require some form of therapeutic intervention; severe is defined as symptoms resulting in marked impairment of function): Cough Sore throat Headache Nasal congestion Body aches and pains Fatigue Additional Inclusion criteria for moderate cases: Patients with the interval between symptoms onset and randomization is no more than 10 days Chest imaging (CT as first option or X-ray if CT not possible)-documented pneumonia Patients with pyrexia (axillary ? 98.6°F or oral ? 99.5°F); respiratory rate > 20 to

Exclusion Criteria

Exclusion Criteria	
Details	Subjects meeting any of the following criteria must not be enrolled in the study: Where, in the opinion of the investigator, participation in this study will not be in the best interest of the subject, or any other circumstances that prevent the subject from participating in the study safely. Severe infection, defined as need for invasive or non-invasive ventilator support, ECMO or shock requiring vasopressor support. Inability to intake or tolerate oral medications. Severe liver disease: underlying liver cirrhosis or alanine aminotransferase (ALT)/aspartate aminotransferase (AST) elevated over 5 times the ULN. Gout/history of gout or hyperuricemia (above the ULN). Prolonged QT, defined as QTcF ? 450 milliseconds for men and as QTcF ? 470 for women Known severely reduced LV function (Ejection fraction Oxygen saturation (SPO2) ? 93 % or arterial oxygen partial pressure (PaO2)/ fraction of inspired O2 (FiO2)? 300 mmHg; Requires ICU care for management of ongoing clinical status. Known allergy or hypersensitivity to Favipiravir; Known severe renal impairment [creatinine clearance (CrCl) Asthma or chronic obstructive lung disease Psychiatric disease that is not well controlled (controlled defined as

	stable on a regimen for more than one year). Pregnant or lactating women; Having used Favipiravir or participated in any other interventional drug clinical study within 30 days prior to first dose of study drug. Clinical prognostic non-survival, palliative care, and have no response to supportive treatment within three hours of admission.

Method of Generating Random Sequence	Stratified randomization
Method of Concealment	Centralized
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
Time until cessation of oral shedding of SARS-CoV-2 virus [Time Frame: Up to 28 days] (Time in days from randomization to a negative SARS-CoV2 RT-PCR result of both oropharyngeal swab and nasopharyngeal swab).	Up to 28 days

Secondary Outcome

Outcome	Timepoints
Time from randomization to clinical cure based on clinician assessment (Recovery of fever, respiratory rate, oxygen saturation and cough relief that is maintained for at least 72 hours; defined as(axillary temperature ? 97.8°F; respiratory rate ? 20 times/min; Oxygen saturation ? 98% without oxygen supplementation; mild or no cough) [For those patients who presented with clinical signs and symptoms at baseline]	From randomization to clinical cure (or day 28; whichever is earlier)
Rate of Clinical cure at day 4/7/10/14	On day 4/7/10/14
Rate of SARS-CoV2 RT-PCR negativity in both oropharyngeal swab and nasopharyngeal swab at day 4/7/10/14	On day 4/7/10/14
Time from randomization to first time use of high flow supplemental oxygen/non-invasive ventilation/mechanical ventilation/ extracorporeal membrane oxygenation	From randomization to first use of high flow supplemental oxygen/non-invasive ventilation/mechanical ventilation/ extracorporeal membrane oxygenation (or day 28, which ever is earlier)
Time from randomization to hospital discharge	Randomization to hospital discharge (or day 28, which ever is earlier)
Frequency of serious adverse events	Randomization to hospital discharge (or day 28, which ever is earlier)

Target Sample Size	**Total Sample Size=**150 **Sample Size from India=**150 **Final Enrollment numbers achieved (Total)=**150 **Final Enrollment numbers achieved (India)=**150
Phase of Trial	Phase 3
Date of First Enrollment (India)	20/05/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable

Recruitment Status of Trial (India)	Completed
Publication Details	NIL
Brief Summary	Glenmark proposes to conduct the current study of favipiravir in mild to moderate COVID-19 patients in India in line with global trials ongoing for this drug. This is a phase 3, open label, randomized, multicentre study .The primary objective of this study is to evaluate the clinical efficacy of favipiravir combined with standard supportive care compared with standard supportive care alone. 150 eligible patients will be randomized in a 1:1 ratio The randomization will be stratified based on baseline disease severity. The study includes 3 days of screening period and maximum 14 days of treatment period. The total duration of study participation will be a maximum of 28 days from the day of randomization.