Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Evaluation the efficacy and safety of Favipiravir made by Shahid Beheshti University of Medical Sciences in comparison with Lopinavir-ritonavir in COVID-19 patients

Protocol summary

Study aim
Evaluation the efficacy and safety of Favipiravir Administration in comparison with Lopinavir-ritonavir in COVID-19 patients
Design
Prospective clinical trial with parallel randomized groups
Settings and conduct
Dr. Masih Daneshvari Hopital
Participants/Inclusion and exclusion criteria
Patients who diagnosed with COVID-19 by RT-PCR test and are over 18 years old. These patients are included if they have oxygen saturation less than 93%, fever more than 72 hours before admission, and bilateral pulmonary infiltration.
Intervention groups
In this study, patients in Favipiravir group receive Favipiravir (Toliddaru-Sobhan Oncology company, Iran) at dose of 1600 mg BID for one day and then 600 mg BID for totally 7 days. In Lopinavir-ritonavir group, patients receive Lopinavir-ritonavir (Heterd company, India) at dose of 200/50 mg two tablets BID for 7 days. The other standard and supportive treatment will be done for both groups similarly.
Main outcome variables
Fever, cough, dyspnea, hospitalization time, changes on lung radiology findings

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20151227025726N14**
Registration date: **2020-04-10, 1399/01/22**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-10, 1399/01/22**
Update count: **0**
Registration date
2020-04-10, 1399/01/22

Registrant information
Name
Farzaneh Dastan
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 912 270 5933
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-04-05, 1399/01/17
Expected recruitment end date
2020-07-07, 1399/04/17
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation the efficacy and safety of Favipiravir made by Shahid Beheshti University of Medical Sciences in comparison with Lopinavir-ritonavir in COVID-19 patients

Public title
Evaluation the effects of Favipiravir in COVID-19 patients
Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Laboratory confirmed COVID-19 with RT-PCR Age over 18 years old Oxygen saturation < 93% Fever more than 72 hours before admission Bilateral pulmonary infiltration

Exclusion criteria:

Chronic kidney Disease Acute kidney Injury Pregnancy or breastfeeding Drug allergy history Chronic liver disease Mild phase of COVID-19 Critical phase of COVID-19

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method was used in this study. 21 blocks including 4 patients generated with online website. In each block, two patients will be assigned to Favipiravir group and two patients will be assigned to Lopinavir-ritonavir group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice-Chancellor in Research Affairs - Shahid Beheshti University of Medical Sciences

Street address

3 rd floor, School of Medicine, Evin St, Shahid Chamran Highway

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Tehran

Province

Tehran

Postal code

1983963113

Approval date

2020-03-28, 1399/01/09

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.011

Health conditions studied

1

Description of health condition studied

COVID-19 pneumonia

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Fever

Timepoint

Daily

Method of measurement

Thermometer

2

Description

Cough

Timepoint

Daily

Method of measurement

Observation

3

Description

Dyspnea

Timepoint

Daily

Method of measurement

Observation

Secondary outcomes

1

Description

Hospitalization duration

Timepoint

At admission time and discharge time

Method of measurement

Clinical records

2

Description

Lung radiology changes

Timepoint

At admission time and seven and 14 days later

Method of measurement

Computed tomography

3

Description
Adverse Drug Reaction
Timepoint
Daily
Method of measurement
Observation

4

Description
Virological clearance
Timepoint
At admission time and seven and 14 days later
Method of measurement
Reverse transcription polymerase chain reaction

5

Description
Death
Timepoint
At end of the study
Method of measurement
Medical Record

6

Description
Needs of mechanical ventilation
Timepoint
Daily
Method of measurement
Medical Record

Intervention groups

1

Description
Intervention group: Favipiravir (Toliddaru-Sobhan Oncology company, Iran) at dose of 1600 mg BID for one day and then 600 mg BID for totally 7 days with the standard and supportive care
Category
Treatment - Drugs

2

Description
Control group: Lopinavir-ritonavir (Heterd company, India) at dose of 200/50 mg two tablets BID for 7 days with the standard and supportive care
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Payam Tabarsi
Street address
Daraabad, Shahid Bahonar St. (Niavaran), Masih Daneshvari Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
3rd floor, School of Medicine, Evin St, Shahid Chamran Highway
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1983963113
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mpd@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person
Hossein Vahidi

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Assisstant Professor, Clinical Pharmacy Specialist

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alisaffaei.ss@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
All potential data can be shared after blinding

When the data will become available and for how long
Six mounts after publishing

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
For research purposes and meta-analysis studies

From where data/document is obtainable
Dr. farzaneh Dastan, Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran

What processes are involved for a request to access data/document
Official letter to the researchers

Comments