

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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

Email address

f_dastan@sbmu.ac.ir

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

City

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

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2712 3000

Email

payamtabarsi@yahoo.com

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

City

Tehran

Province

Tehran

Postal code

1983963113

Phone

+98 21 23871

Email

mpd@sbm.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
Street address
Valieasr St., Intersection of Niyayesh Highway, Shahid
Beheshti University of Medical Sciences, Faculty of
Pharmacy
City
Tehran
Province
Tehran
Postal code
1991953381
Phone
+98 21 8820 0118
Email
h.vahidi@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Farzaneh Dastan
Position
Assistant Professor, Clinical Pharmacy Specialist
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Valieasr St., Intersection of Niyayesh Highway, Shahid
Beheshti University of Medical Sciences, Faculty of
Pharmacy
City
Tehran
Province
Tehran
Postal code
1991953381
Phone
+98 21 8820 0118
Fax
Email
f_dastan@sbmu.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences
Full name of responsible person
Ali Saffaei
Position
Clinical Pharmacy Resident
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
Niayesh Highway., Valiasr Ave.
City
Tehran
Province
Tehran
Postal code
1991953381
Phone
+98 21 8820 0118
Email
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 months 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