

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 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

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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

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

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1983963113

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+98 21 23871

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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  
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Valieasr St., Intersection of Niyayesh Highway, Shahid  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
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Farzaneh Dastan  
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Assistant Professor, Clinical Pharmacy Specialist  
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## Person responsible for updating data

### Contact

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Shahid Beheshti University of Medical Sciences  
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Ali Saffaei  
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Clinical Pharmacy Resident  
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Medical doctor  
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Niayesh Highway., Valiasr Ave.  
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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 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