

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Favipiravir effectiveness in patients undergoing COVID19 Acute respiratory distress syndrome (ARDS)

Protocol summary

Study aim

Evaluation of the pharmacological effect of Favipiravir in reducing mortality and improving oxygenation

Design

Patients admitted to the intensive care unit with a pao₂ to fio₂ ratio of less than 300 and having a bilateral infiltration in the chest x ray were included in the plan. And oxygenation and chest x ray and symptoms of the disease including fever and headache were recorded And in case of death or discharge, a note was made

Settings and conduct

Patients admitted to the intensive care unit, as soon as they entered the plan, entered the study and were treated if they were satisfied.

Participants/Inclusion and exclusion criteria

Entry requirement: age over 18 years Positive covid patients The ratio of pao₂ to fio₂ is below 300 No entry condition: Dissatisfaction with entering the plan

Intervention groups

Patients with a pao₂ to fio₂ ratio of less than 300 and who have bilateral infiltration in the chest x ray were included in the study. On the first day, 3200 mg for first day and 1600 mg of the drug were given twice daily in the morning and evening for seven days. Chest x ray and symptoms of the disease, including fever and headache, were recorded

Main outcome variables

Oxygenation and chest x ray

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150107020592N26**

Registration date: **2020-06-15, 1399/03/26**

Registration timing: **retrospective**

Last update: **2020-06-15, 1399/03/26**

Update count: **0**

Registration date

2020-06-15, 1399/03/26

Registrant information

Name

Seyed Mohammad Reza Hashemian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2610 9944

Email address

iran.criticalcare@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

2020-03-20, 1399/01/01

Actual recruitment end date

2020-05-21, 1399/03/01

Trial completion date

2020-05-21, 1399/03/01

Scientific title

Favipiravir effectiveness in patients undergoing COVID19 Acute respiratory distress syndrome (ARDS)

Public title

Favipiravir effectiveness in patients undergoing COVID19 Acute respiratory distress syndrome (ARDS)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Positive covid patients Patients with a pao2 to fio2 ratio below 300 Age over 18 years

Exclusion criteria:

Lack of desire to enter the plan

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **20**

Actual sample size reached: **20**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Masih Daneshvari Hospital the Edjucational , Research and Treatment center

Street address

End of Niavaran, Darabadational , Research and Treatment center.

City

Tehran

Province

Tehran

Postal code

1956944413

Approval date

2020-04-07, 1399/01/19

Ethics committee reference number

IR.SBMU.NRITLD.REC.1399.041

Health conditions studied

1

Description of health condition studied

covid positive

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

oxygenation

Timepoint

Up to 10 consecutive days

Method of measurement

pulse Oximetry

Secondary outcomes

1

Description

mortality

Timepoint

Completion of treatment

Method of measurement

death

Intervention groups

1

Description

Intervention group:Patients with a pao2 to fio2 ratio of less than 300 and who have bilateral infiltration in the chest x ray were included in the study. On the first day, 3200 mg for first day and 1600 mg of the drug were given twice daily in the morning and evening for seven days. Chest x ray and symptoms of the disease, including fever and headache, were recorded

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Seyyed Mohammadreza Hashemian

Street address

Masih Daneshvari Hospital, Darabad, Niavaran Sq, Tehran, Iran

City

Tehran

Province

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1956944413

Phone

+98 21 2712 2265

Email

iran.criticalcare@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Masih Daneshvari Hospital

Full name of responsible person

DR Reza Masoodi

Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran

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1956944413

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+98 21 2912 3100

Email

iran.criticalcare@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Masih Daneshvari Hospital

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

Seyed Mohammad Reza Hashemian

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Masih Daneshvari Hospital, Darabad, Niavaran Street, Tehran, Iran

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Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Mohammad Reza Hashemian

Position

Associate Professor

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Fax**Email**

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Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Mohammad Reza Hashemian

Position

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Latest degree

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Postal code

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Phone

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Fax**Email**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All patient information can be published after deleting the name

When the data will become available and for how long

It will take a month from the time of application

To whom data/document is available

All professors of medical universities in the country

Under which criteria data/document could be used

Help advance science

From where data/document is obtainable

professor hashemian in masih daneshvari hospital

What processes are involved for a request to access data/document

one month

Comments