Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 plane. 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

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

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Masih Daneshvari Hospital
Full name of responsible person
DR Reza Masoodi
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Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran
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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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Person responsible for updating data

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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