

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Study the effect of Favipiravir on the outpatient treatment Covid-19 patients

Protocol summary

Study aim

Study the effect of Favipiravir on the outpatient treatment Covid-19 patients

Design

70 outpatient patients with covid-19 will be randomly assigned to intervention and control (placebo) groups. randomization will be done by simple randomization via www.randomization.com. This is a phase 3 trial with parallel groups and triple blinded.

Settings and conduct

This study will be held in 3 outpatient center. Blinding will be triple blind, so that neither patient, physician, the outcome assessor and data analyzer are not aware of the groups. patients in intervention and placebo groups will be treated for 5 days and followed for 1 month.

Participants/Inclusion and exclusion criteria

Inclusion criteria: definite case of Covid-19, age over 18, presented within 5 days from the start of sign and symptoms; Exclusion criteria: severe cases with SpO2 under 90, using an antiviral in previous two weeks, previous infection with covid-19, using an steroid in previous two weeks, being under treatment with steroid, previous allergic to Favipiravir, renal failure, hepatic failure, pregnancy, lactating.

Intervention groups

Intervention: Favipiravir 200 miligram, 8 pills daily for 5 days; Control: Placebo, 8 pills daily for 5 days

Main outcome variables

Treatment failure, Side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171219037964N3**

Registration date: **2020-12-02, 1399/09/12**

Registration timing: **prospective**

Last update: **2020-12-02, 1399/09/12**

Update count: **0**

Registration date

2020-12-02, 1399/09/12

Registrant information

Name

Babak Amra

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 0048

Email address

amra@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of Favipiravir on the outpatient treatment Covid-19 patients

Public title

Effect of Favipiravir on outpatient treatment of Covid-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

definite case of Covid-19 age over 18 presented within 5

days from the start of sign and symptoms

Exclusion criteria:

severe cases with SpO2 under 90 using an antiviral in previous two weeks previous infection with covid-19 using an steroid in previous two weeks being under treatment with steroid previous allergic to Favipiravir renal failure hepatic failure pregnancy lactating

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using simple randomization. A random string will be made using www.randomization.com for 70 number in two groups. each patient will be assigned with a number by the physician. then this number will be matched by the random string by research assistant and the patient will be assigned to group A or B according to that

Blinding (investigator's opinion)

Triple blinded

Blinding description

patients will be assigned to groups Intervention (favipiravir) or Control (placebo). placebo is designed just the same as favipiravir and in a same pack. packages is defined by A or B and neither of patient, physician, researchers, outcome assessor and data analyzer do not know the meaning of codes. Just the research asisstant is aware of codes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezarjerib St.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-12-01, 1399/09/11

Ethics committee reference number

IR.MUI.MED.REC.1399.780

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

U07.1

ICD-10 code description

U07COVID-19, virus identified

Primary outcomes

1

Description

treatment failure

Timepoint

days 3, 7, 14, 21, 28 from the start of treatment

Method of measurement

interview with patients

2

Description

side effects

Timepoint

days 3 and 7 after the start of treatment

Method of measurement

interview with patients

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients in this group will be treated by Favipiravir 200miligram, 8 pills (2 pills, 4 times a day) for 5 days

Category

Treatment - Drugs

2

Description

Control group: patients in this group receive placebo, 8

pills daily for 5 days
Category
Placebo

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salahimehrdad@yahoo.com

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr. Amra clinic
Full name of responsible person
Dr. Babak Amra
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Sepahsalar St.
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Postal code
8166863543
Phone
+98 31 3776 6293
Email
amrababak@gmail.com

2

Recruitment center

Name of recruitment center
Dr. soltaninejad clinic
Full name of responsible person
Dr. Forough Soltaninejad
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No. 409, Noor building, Shamsabadi St.
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Isfahan
Province
Isfahan
Postal code
8134654669
Phone
+98 31 3224 0059
Email
f.soltaninejad@med.mui.ac.ir

3

Recruitment center

Name of recruitment center
Dr. Salahi clinic
Full name of responsible person
Dr. Mehrdad Salahi
Street address
First floor, Iranian Clinic, Ferdosi St.
City
Shahinshar
Province
Isfahan
Postal code
8314896713
Phone

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh haghjooy Javanmard
Street address
Hezarjerib St.
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8174673461
Phone
+98 31 3792 3060
Email
research@mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Babak Amra
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Respiratory disease
Street address
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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

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Person responsible for updating data

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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 data can be shared after being unidentified

When the data will become available and for how long

one month after the publication of results

To whom data/document is available

All researches are allowed to apply for the data

Under which criteria data/document could be used

For using in systematic review analysis

From where data/document is obtainable

email to amrababak@gmail.com

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

The application email will be sent to the chancellor for research of Isfahan University of Medical Sciences, after the approval the data will be sent to the applicant

Comments