

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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](http://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 a 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 milligram, 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

+98 31 4527 0780  
**Email**  
salahimehrdad@yahoo.com

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**  
Dr. Amra clinic  
**Full name of responsible person**  
Dr. Babak Amra  
**Street address**  
Sepahsalar St.  
**City**  
Isfahan  
**Province**  
Isfahan  
**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  
**Street address**  
No. 409, Noor building, Shamsabadi St.  
**City**  
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.  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
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**  
Isfahan University of Medical Sciences, Hezarjerib St.  
**City**  
Isfahan  
**Province**

Isfahan  
**Postal code**  
8174673461  
**Phone**  
+98 31 3668 0048  
**Fax**  
**Email**  
Amra@med.mui.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Babak Amra  
**Position**  
Professor  
**Latest degree**  
Subspecialist  
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**Phone**  
+98 31 3668 0048  
**Fax**  
**Email**  
Amra@med.mui.ac.ir

## Person responsible for updating data

### 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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Isfahan  
**Province**  
Isfahan  
**Postal code**  
8174673461  
**Phone**  
+98 31 3668 0048  
**Fax**  
**Email**  
Amra@med.mui.ac.ir

## 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