# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Nov 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**

Isfehan

**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

## 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**

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**Province**

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**Postal code**

8166863543

**Phone**

+98 31 3776 6293

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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**

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**Postal code**

8134654669

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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**

Isfehan

**Postal code**

8314896713

**Phone**

+98 31 4527 0780

**Email**

salahimehrdad@yahoo.com

## 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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**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

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## Person responsible for scientific inquiries

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**Other areas of specialty/work**
Respiratory disease

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## Person responsible for updating data

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Esfahan University of Medical Sciences

**Full name of responsible person**
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**Position**
Professor

**Latest degree**
Subspecialist

**Other areas of specialty/work**
Respiratory disease

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**Fax**

**Email**
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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**