

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 2026

### EVALUATION OF THE EFFECT OF FAVIPRAVIR ON MANAGEMENT PATIENT WITH COVID-19

#### Protocol summary

##### Study aim

Efficacy of Favipiravir in management of patient with COVID-19

##### Design

This is a double blind clinical trial study in phase 3 with 114 patients with COVID19 that randomly divided into 2 groups.

##### Settings and conduct

This is a double blind clinical trial study with 114 patients with positive PCR for COVID19 that have referred to Khansari and Valiasr hospital and they are in subgroup 3 of hospitalization. They will be divided into 2 groups (Favipiravir and control) randomly.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with COVID19 referred to Khansari and Valiasr hospital Patients with COVID19 in subgroup 3 of hospitalization (i.e SPO2 less than 80% or PaO2 less than 60 CmH2O, severe respiratory distress and respiratory rate more than 34 per minute, instable hemodynamic, acid base disturbance, similar to moderate to severe cases) Exclusion criteria: Pregnancy Drug reaction Deterioration of symptoms after drug usage Renal failure manifestation Heart failure manifestation

##### Intervention groups

Patients in Favipiravir group will be received Favipiravir tablet for 7 days. Patients in control group will be received placebo (flour tablet) for 7 days.

##### Main outcome variables

severity of COVID19

#### General information

##### Reason for update

##### Acronym

COVID-19

##### IRCT registration information

IRCT registration number: **IRCT20201028049175N1**

Registration date: **2020-12-12, 1399/09/22**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-12-12, 1399/09/22**

Update count: **0**

##### Registration date

2020-12-12, 1399/09/22

##### Registrant information

###### Name

Shamim Valibak

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3417 3502

###### Email address

sh.valibak@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-11-21, 1399/09/01

##### Expected recruitment end date

2021-02-19, 1399/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

EVALUATION OF THE EFFECT OF FAVIPRAVIR ON MANAGEMENT PATIENT WITH COVID-19

##### Public title

EVALUATION OF THE EFFECT OF FAVIPRAVIR ON MANAGEMENT PATIENT WITH COVID-19

##### Purpose

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
All of patients with COVID19 referred to Valiasr and Khansari hospital All of patients in subgroup 3 of hospitalization

**Exclusion criteria:**  
Patients that present allergic reaction to the drug  
Patients with deterioration of symptoms after drug usage  
Renal failure manifestation in patients  
Heart failure manifestation in patients  
Pregnancy

**Age**  
No age limit

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**  
Target sample size: **114**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patients will be allocated into two groups using a permuted balanced block randomization method with the size of blocks 4 and 6. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Concealment is also guaranteed due to the use of permuted balanced block randomization method.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
In this study patients are blind, as one group will receive Favipiravir and control group will receive flour tablet that is similar to Favipiravir. In addition, data analyser is blind about groups of patients.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**  
Ethics committee of Arak University of Medical Sciences

**Street address**  
Assistance of research and technology, Payambare

azam institution, Arak University of Medical Sciences, Sardasht street

**City**  
Arak

**Province**  
Markazi

**Postal code**  
3848176341

**Approval date**  
2020-08-02, 1399/05/12

**Ethics committee reference number**  
IR.ARAKMU.REC.1399.179

## Health conditions studied

### 1

#### Description of health condition studied

Coronavirus disease 2019 (COVID19)

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID-19, virus identified

## Primary outcomes

### 1

#### Description

Severity of coronavirus 2019

#### Timepoint

Before prescription of drug and then every day until 7 days

#### Method of measurement

pulse oximetry, respiratory rate, heart rate, CT scan

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Favipiravir tablet of FUJIFILM company will be given to the patients. The dose is 1600 mg twice daily on first day and days 2-7: 600 mg twice daily.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Placebo drug (flour tablet) will be given to the patients orally twice daily for 7 days.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**  
Khansari hospital  
**Full name of responsible person**  
Hossein Sarmadian  
**Street address**  
The end of Daneshgah street  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
3818649433  
**Phone**  
+98 86 3367 5001  
**Email**  
research@arakmu.ac.ir

### 2

#### Recruitment center

**Name of recruitment center**  
Valiasr hospital  
**Full name of responsible person**  
Behnam Mahmoudieh  
**Street address**  
Valiasr square  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
3814957558  
**Phone**  
+98 86 3222 2003  
**Email**  
pr\_valieasr@arakmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Assistance of research and technology of Arak university of medical science-Dr.Alireza Kamali  
**Street address**  
Assistance of research and technology, Payambare azam institution, Arak University of Medical Sciences, Sardasht street  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
3848176341

**Phone**  
+98 86 3417 3639  
**Email**  
research@arakmu.ac.ir

**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Arak 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**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Behnam Mahmoudieh  
**Position**  
Assistant professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Valiasr hospital, Valiasr square  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
3814957558  
**Phone**  
086-32222003-8  
**Email**  
behnammahmoodiyeh@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Alireza Kamali  
**Position**  
lecturer  
**Latest degree**  
Specialist  
**Other areas of specialty/work**

Anesthesiology

**Street address**

Valiasr hospital, Valiasr square

**City**

Arak

**Province**

Markazi

**Postal code**

3814957558

**Phone**

086-32222003-8

**Email**

alikalaliir@yahoo.com

**Province**

Markazi

**Postal code**

3814957558

**Phone**

086-32222003-8

**Email**

sh.valibak@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Shamim Valibak

**Position**

General physician non-faculty

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Valiasr hospital, Valiasr square

**City**

Arak

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available