# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

28 Jun 2026

## Evaluation of safety and effectiveness of favipiravir in comparison with Tenofovir Alafenamid in hospitalized patients with COVID-19

### Protocol summary

**Study aim**
Evaluation of safety and effectiveness of favipiravir in comparison with Tenofovir Alafenamid in hospitalized patients with COVID-19

**Design**
Clinical trial, with two arm parallel group, randomized, Open-label study, phase 2 on 100 patients that randomly assigned to one of the two groups and patients will receive their drugs by presenting the envelope containing the code.

**Settings and conduct**
This study is a clinical trial that will be performed in Imam Khomeini Hospital of Ardabil in patients with Covid 19 who are hospitalized in the ward and have moderate to severe severity. Patients were selected based on the inclusion criteria and randomly divided into two groups receiving favipiravir and tenofovir alafenamid.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Diagnosis of COVID-19 based on chest CT scan or positive PCR test for COVID-19; Requiring hospitalization; Patient's age between 16 and 100 years; Signed informed consent form; Exclusion criteria: Receiving other antiviral medications; renal failure; HIV; Pregnancy and Lactation.

**Intervention groups**
Intervention group: Group receiving, Stat dose of eight 200 mg Favipiravir (Nafas farmed Co, Iran) tablets followed by Favipiravir 600 mg three times a day for 7 days. Control group: Group receiving Tenofovir alafenamid (Bakhtar bioshimi Co, Iran), regimen. 25 mg for 7 days.

**Main outcome variables**
Mortality, length of stay in hospital

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20150808023559N23**
Registration date: **2020-10-11, 1399/07/20**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-11, 1399/07/20**
Update count: **0**

**Registration date**
2020-10-11, 1399/07/20

**Registrant information**

**Name**
Somaieh Matin

**Name of organization / entity**
Ardabil University of Medicine Sciences

**Country**
Iran (Islamic Republic of)

**Phone**
+98 45 3373 3011

**Email address**
s.matin@arums.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-09-20, 1399/06/30

**Expected recruitment end date**
2020-11-20, 1399/08/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Evaluation of safety and effectiveness of favipiravir in comparison with Tenofovir Alafenamid in hospitalized patients with COVID-19

**Public title**
Effectiveness of favipiravir in comparison with Tenofovir Alafenamid in patients with COVID-19
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Diagnosis of COVID-19 based on chest CT scan or positive PCR test for COVID-19 Requiring hospitalization Patient's age between 16 and 100 years Signing informed consent form
**Exclusion criteria:**
Receiving other antiviral medicationsrenal failure Pregnancy HIV Lactation Renal failure
**Age**
From **16 years** old to **100 years** old
**Gender**
Both

**Phase**
2
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **100**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Randomization method is a simple randomizing using a table of random numbers, a set of numbers which is completely generated randomly without any specific pattern or order in a table form. Table numbers are read from the left, in a way that even numbers are assgined to intervention A and odd numbers to intervention B. In this way, the researcher touches one of the numbers and moves to the right, then records the numbers and assigns them to different groups. Next, considering the volume of the research sample, aluminum wrapper envelopes are prepared (in order not to clarify the content of the envelopes), each of the random sequences is recorded on a card and placed inside an envelope.To maintain a random sequence, envelopes are numbered in the same way. Finally, the flap of the envelopes are sealed and respectively placed inside a box. To reveal the participants' assigned group, at the beginning of the registration based on the order of eligible participants entry to study, one of the envelopes is opened.
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Ardabil University of Medical Sciences
**Street address**
Ardabil University of Medicine Sciences, Daneshgah street, Ardabil
**City**
Ardabil
**Province**
Ardabil
**Postal code**
5615783134
**Approval date**
2020-04-11, 1399/01/23
**Ethics committee reference number**
IR.ARUMS.REC.1399.310

## Health conditions studied

### 1

**Description of health condition studied**
COVID-19
**ICD-10 code**
U07.1
**ICD-10 code description**
COVID-19

## Primary outcomes

### 1

**Description**
Hospital mortality
**Timepoint**
Up to two weeks after the intervention on a daily basis
**Method of measurement**
Patient medical records

## Secondary outcomes

### 1

**Description**
Duration of hospitalization
**Timepoint**
From the time of hospitalization to the patient's discharge from the hospital
**Method of measurement**
Patient medical records

## Intervention groups

### 1

**Description**

Intervention group: Group receiving Favipiravir. This group will receive stat dose of eight 200 mg Favipiravir tablets(Nafas farmed Co, Iran) followed by Favipiravir 600 mg three times a day for 7 days. This regimen could be continued for 10 days if necessary according to clinical response of the patient.

**Category**
Treatment - Drugs

**2**

**Description**
Control group: will receive Tenofovir alafenamid (Bakhtar bioshimi Co, Iran) 25 mg for 7 days.

**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Imam Khomeini Hospital

**Full name of responsible person**
Somaieh Matin

**Street address**
Imam Khomeini Hospital, Shahid Jeddi Street, Ardabil

**City**
Ardabil

**Province**
Ardabil

**Postal code**
5314156198

**Phone**
+98 45 3325 1410

**Email**
s.matin@arums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Ardabil University of Medical Sciences

**Full name of responsible person**
Dr Farhad Pourfarzi

**Street address**
Ardabil University of Medical Science, Daneshgah street, Ardabil, Iran

**City**
Ardabil

**Province**
Ardabil

**Postal code**
۵۶۱۸۹۸۵۹۹۱

**Phone**
+98 45 3352 2247

**Email**
F.pourfarzi@arums.ac.ir

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Ardabil 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**
Ardabil University of Medical Sciences

**Full name of responsible person**
Somaieh Matin

**Position**
Assistant Professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Internal Medicine

**Street address**
Imam Khomeini Hospital, Shahid Jeddi street, Ardabil

**City**
Ardabil

**Province**
Ardabil

**Postal code**
53141 56198

**Phone**
+98 45 3325 1410

**Email**
s.matin@arums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Ardabil University of Medical Sciences

**Full name of responsible person**
Somaieh Matin

**Position**
Assistant Professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Internal Medicine

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**Email**
s.matin@arums.ac.ir

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Ardabil University of Medical Sciences
**Full name of responsible person**
Somaieh Matin
**Position**
Assistant Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Internal Medicine
**Street address**
Imam Khomeini Hospital, Ardabil University of Medical Science, Ardabil
**City**
Ardabil
**Province**
Ardabil
**Postal code**
5314156198
**Phone**
+98 45 3325 1410
**Email**
s.matin@arums.ac.ir

## 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