

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 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 medications renal 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 assigned 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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Imam Khomeini Hospital, Shahid Jeddi street, Ardabil

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Phone

+98 45 3325 1410

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

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