Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 45 3373 3011

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ardabil University of Medical Sciences

Full name of responsible person
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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

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Position
Assistant Professor

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Person responsible for updating data

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Specialist
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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