

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation of safety and efficacy of hydroxychloroquine plus favipiravir drug regimen in comparison with hydroxychloroquine plus kaletra in hospitalized patients with COVID-19

Protocol summary

Study aim

Comparing safety and efficacy of Favipiravir and Kaletra in COVID-19

Design

In this intervention study, 100 patient who have Inclusion criteria will be divided into two groups using block randomization method (n=50 in each group). Proper counseling will be done and a written informed consent will be obtained before starting the treatment regimen.

Settings and conduct

The design is a clinical trial that will be conducted Emam Khomeini hospital in Ardabil - Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of COVID-19 based on either ground glass appearance in chest CT scan or positive RT-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 Favipiravir plus Hydroxychloroquine. Stat dose of eight 200 mg Favipiravir tablets (total 1600 mg) followed by Favipiravir 600 mg three times a day for 7 days plus Hydroxychloroquine 200mg two times per day for 7 days. Control group: Group receiving Kaletra plus Hydroxychloroquine regimen. Stat dose of two 200 mg Hydroxychloroquine tablets (total 400 mg) followed by Kaletra(Lopinavir/Ritonavir) 200/50 mg two times a day for 7 days.

Main outcome variables

Mortality, length of stay in hospital

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150808023559N20**

Registration date: **2020-04-11, 1399/01/23**

Registration timing: **prospective**

Last update: **2020-04-11, 1399/01/23**

Update count: **0**

Registration date

2020-04-11, 1399/01/23

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

2020-04-29, 1399/02/10

Expected recruitment end date

2020-07-31, 1399/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of safety and efficacy of hydroxychloroquine plus favipiravir drug regimen in comparison with hydroxychloroquine plus kaletra in hospitalized patients with COVID-19

Public title

Efficacy of hydroxychloroquine plus favipiravir drug regimen in comparison with hydroxychloroquine plus kaletra in hospitalized patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of COVID-19 based on either ground glass appearance in chest CT scan or positive RT-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 Pregnancy HIV Lactation

Age

From **16 years** old to **100 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use block randomization methods using variable block size of four stratified .

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

2020-04-08, 1399/01/20

Ethics committee reference number

IR.ARUMS.REC.1399.012

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

Death

Timepoint

At the time of discharge from the hospital

Method of measurement

Patient medical records

Secondary outcomes

1

Description

Hospital stay

Timepoint

End of intervention

Method of measurement

Patient medical records

Intervention groups

1

Description

Intervention group: Group receiving Favipiravir (Nafas farmed Co, Iran) plus Hydroxychloroquine (Iran daroo Co, Iran). This group will receive stat dose of eight 200 mg Favipiravir tablets (total 1600 mg) followed by Favipiravir 600 mg three times a day for 7 days plus Hydroxychloroquine 200mg two times per day for 7 days. This regimen could be continued for 10 days if necessary according to clinical response of the patient. Other supportive and routine care will be the same in both groups.

Category

Treatment - Drugs

2

Description

Control group: Group receiving Kaletra (Bakhtar bioshimi Co, Iran) plus Hydroxychloroquine (Iran daroo Co, Iran) regimen. This group will receive Stat dose of two 200 mg Hydroxychloroquine tablets (total 400 mg) followed by Kaletra(Lopinavir/Ritonavir) 50/200 mg two times a day for 7 days, This regimen could be continued for 10 days if necessary according to clinical response of the patient. Other supportive and routine care will be the same in both groups.

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. Shahab Bohlooli

Street address

Ardabil University of Medical Science, Daneshgah street, Ardabil, Iran

City

ARDABIL

Province

Ardabil

Postal code

۵۶۱۸۹۸۵۹۹۱

Phone

+98 45 3352 2247

Email

shahab.bohlooli@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

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+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
Postal code

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