

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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**

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**Province**

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**Postal code**

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**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

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**Postal code**

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**Email**

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## 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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## 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