Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Oct 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)

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+98 45 3373 3011

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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

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Imam Khomeini Hospital, Shahid Jeddi Street, Ardabil

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Dr. Shahab Bohloli

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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

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Person responsible for scientific inquiries

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Position
Assistant Professor

Latest degree
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Person responsible for updating data

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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