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 on the need for intensive care unit treatment in patients with COVID-19; a randomized, multicenter, parallel groups, open label study

Protocol summary

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

Design
Randomized parallel group, clinical trial, open label

Settings and conduct
The design is a multicenter clinical trial that will be conducted in 20 centers all over the country.

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 such as (Kaletra, Ribavirin, Oseltamivir); Chronic liver or renal failure; HIV; GI bleeding; Pregnancy; Lactation; QT interval > 500 ms.

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
Admission to intensive care unit, In-hopital mortality, length of stay in hospital, Radiological Treatment Response (CT scan), Laboratory Treatment Response (return of blood cell count and CRP values to normal) , Clinical improvement, Oxygen saturation after discontinuation of supplemental oxygen for 5 minutes, Oxygen therapy maximum flow during the day (lit/min), and Adverse and allergic drug reactions

General information

Reason for update
Announcing the Trial completion date

Acronym

IRCT registration information
IRCT registration number: **IRCT20200318046812N1**
Registration date: **2020-04-01, 1399/01/13**
Registration timing: **prospective**

Last update: **2020-09-19, 1399/06/29**
Update count: **6**

Registration date
2020-04-01, 1399/01/13

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-01, 1399/01/13

Expected recruitment end date
2020-06-02, 1399/03/13

Actual recruitment start date

2020-04-02, 1399/01/14

Actual recruitment end date

2020-08-03, 1399/05/13

Trial completion date

2020-08-20, 1399/05/30

Scientific title

Evaluation of safety and efficacy of hydroxychloroquine plus favipiravir drug regimen in comparison with hydroxychloroquine plus kaletra on the need for intensive care unit treatment in patients with COVID-19; a randomized, multicenter, parallel groups, open label study

Public title

Comparison of the safety and efficacy of Favipiravir and kaletra in 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 because of: Patient's oxygen saturation less than 93% OR Requiring hospitalization because of: GCS score less than 15 OR Requiring hospitalization because of: systolic blood pressure less than 100 or 30 mmHg decrease in systolic blood pressure from the level prior to current illness OR Requiring hospitalization because of: renal failure (creatinine 1.5 times the previous measurement in the last 7 days OR Requiring hospitalization because of: liver failure (AST and ALT 3 times upper limit of normal) Patient's age between 16 and 100 years Signed informed consent form.

Exclusion criteria:

Receiving other antiviral medications such as (Kaletra, Ribavirin, Oseltamivir, ...) Chronic liver failure Chronic Renal Failure Patients with acute problems whose survival is expected to be less than 48 hours HIV patients A history of gastrointestinal bleeding Pregnancy and lactation QT interval exceeds 500 ms

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **324**

Actual sample size reached: **424**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use block randomization methods using variable block size of four and six stratified by center. We will use Excel software and rand() function to generate the random sequence. The master randomization list will be kept by the epidemiologist working wit the research team.

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

Iran university of medical sciences

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Iran University of Medical Sciences, Hemmat Highway, Next to Milad Tower, Tehran, Iran

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Province

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Postal code

14665354

Approval date

2020-03-30, 1399/01/11

Ethics committee reference number

IR.IUMS.REC.1399.065

2

Ethics committee

Name of ethics committee

Baqiyatallah university of medical sciences

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Tehran, Vanak Square, Mulla Sadra Street

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Approval date

2020-03-26, 1399/01/07

Ethics committee reference number

IR.BMSU.REC.1399.017

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
Admission to intensive care unit
Timepoint
Once (when admitted to intensive care unit)
Method of measurement
Hospital records

Secondary outcomes

1

Description
In-hopital mortality
Timepoint
once
Method of measurement
Patient medical records

2

Description
length of stay in hospital
Timepoint
Once at discharge
Method of measurement
Patient medical records

3

Description
Radiological Treatment Response (CT scan) , more than 50% reduction in the affected area
Timepoint
CT scan will be done twice (once at the time of admission and the second time 10 days after discharge). Assessment will be done comparing the second CT with the first one
Method of measurement
Patient CT scan

4

Description
Laboratory Treatment Response; return of blood cell count and CRP values to normal
Timepoint
Daily
Method of measurement
Laboratory kits

5

Description
Oxygen saturation without supplemental oxygen. Measurement will be done after discontinuation of oxygen therapy for 5 minutes.
Timepoint
4 times a day while in the wards
Method of measurement
Observation

6

Description
Oxygen therapy maximum flow during the day (lit/min)
Timepoint
Daily
Method of measurement
Patient medical records

7

Description
Allergic drug reaction
Timepoint
Daily
Method of measurement
Adverse Drug Reaction forms

8

Description
Adverse drug reactions
Timepoint
Daily
Method of measurement
Adverse Drug Reaction forms

9

Description
Clinical improvement
Timepoint
Daily
Method of measurement
One of the following may happen to the patient: Oxygen saturation reaches above 93% and stays above 93%, the patient does not need oxygen therapy and stays in the same position, discharge by the treating physician

Intervention groups

1

Description
Intervention group: Group receiving Favipiravir plus Hydroxychloroquine. Stat dose of eight 200 mg Favipiravir tablets (total 1600 mg) and stat dose of two 200mg Hydroxychloroquine tablets (total 400 mg) 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. Other supportive and routine care will be the same in both groups.
Category
Treatment - Drugs

2

Description
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. 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

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Recruitment center

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
50
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

2

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah University of Medical Sciences
Proportion provided by this source
50
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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Deidentified IPD related to outcome will be shared.
When the data will become available and for how long
The access period will begin 6 months after publication of the paper
To whom data/document is available
The data will be available only for academic researchers.
Under which criteria data/document could be used
Only meta-analysis in collaboration with the current study research team will be permitted.
From where data/document is obtainable
Researchers can request data by emailing Dr. Mustafa Qanei (mghaneister@gmail.com) or Dr. Mehdi Bagheri (mbagheri.pharm@gmail.com).
What processes are involved for a request to access data/document
Requested data will be sent by email after consideration and approval by the relevant authorities from Baghiattallah university.
Comments
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