

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 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-hospital 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

Name

Mostafa Ghanei

Name of organization / entity

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Iran (Islamic Republic of)

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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 with 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

Street address

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

City

Tehran

Province

Tehran

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

Street address

Tehran, Vanak Square, Mulla Sadra Street

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1435916471

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-hospital 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

1

Recruitment center

Name of recruitment center

Baqiyatallah university of medical sciences

Full name of responsible person

Dr Behzad Einollahi

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Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

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Recruitment center

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Name of recruitment center

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Recruitment center

Name of recruitment center

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Recruitment center

Name of recruitment center

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Recruitment center

Name of recruitment center
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Name of recruitment center

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Name of recruitment center

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Name of recruitment center

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Name of recruitment center

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Full name of responsible person

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Name of recruitment center

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Recruitment center

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Sponsors / Funding sources

1

Sponsor

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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

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr Mostafa Ghanei

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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

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Hossein Biganeh

Position

Pharmacy Student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Pharmacy Student

Latest degree

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Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr Mostafa Ghanee

Position

Faculty member Baqiyatallah University of Medical
Sciences

Latest degree

Subspecialist

Other areas of specialty/work

pulmonologist

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Person responsible for updating data**Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Hossein Biganeh

Position**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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