

# 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-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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8860 0067

##### Email address

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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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**Province**

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**Postal code**

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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**Web page address**

**2**

**Recruitment center**

**Name of recruitment center**

Firoozgar Hospital

**Full name of responsible person**

Dr Farhad Zamani

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Valiasr Square, Karimkhan Boulevard., Behafarin st.,

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**3**

**Recruitment center**

**Name of recruitment center**

Rasoul Akram Hospital

**Full name of responsible person**

Dr Saeid Kalantari

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Satarkhan, Niayesh St., Maziar Mansouri St.,

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**4**

**Recruitment center**

**Name of recruitment center**

Isfahan Khorshid Hospital

**Full name of responsible person**

Dr Ramin Sami

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**5**

**Recruitment center**

**Name of recruitment center**

Shahid Beheshti

**Full name of responsible person**

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**6**

**Recruitment center**

**Name of recruitment center**

Kosar Hospital

**Full name of responsible person**

Dr Mohamad Memarian

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## 7

**Recruitment center**  
**Name of recruitment center**  
Velaiat Hospital  
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## 8

**Recruitment center**  
**Name of recruitment center**  
Emam khomeini Hospital  
**Full name of responsible person**  
Dr Roya Qasemian  
**Street address**  
Imam Square, Vali Asr Highway  
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## 9

**Recruitment center**  
**Name of recruitment center**  
Labafinejad Hospital  
**Full name of responsible person**  
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## 10

**Recruitment center**  
**Name of recruitment center**  
Shahid Beheshti Hospital  
**Full name of responsible person**  
Dr Akram Asghari  
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## 11

**Recruitment center**  
**Name of recruitment center**  
Forghani Hospital  
**Full name of responsible person**  
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**Recruitment center**  
**Name of recruitment center**  
Kamkar Hospital  
**Full name of responsible person**  
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### 13

#### Recruitment center

**Name of recruitment center**

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#### Recruitment center

**Name of recruitment center**

Emam Reza Hospital

**Full name of responsible person**

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**Name of recruitment center**

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**Full name of responsible person**

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#### Recruitment center

**Name of recruitment center**

Firoozabadi Hospital

**Full name of responsible person**

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#### Recruitment center

**Name of recruitment center**

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**Full name of responsible person**

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### 18

#### Recruitment center

**Name of recruitment center**

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**Full name of responsible person**

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**Province**

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### 19

#### Recruitment center

**Name of recruitment center**

Ganjavian Hospital

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**20****Recruitment center****Name of recruitment center**

Razi Hospital

**Full name of responsible person**

Dr Maryam Haddadzadeh shoushtari

**Street address**

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**Email**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr. seyed Abbas Motevalian

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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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**Postal code**

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**Email**

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Pharmacy Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

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**Province**

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**Postal code**

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**Phone**

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**Email**

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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

**Street address**

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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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