

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Evaluation of the efficiency and safety of favipiravir + hydroxychloroquine drug regimen in comparison with hydroxychloroquine in hospitalized patients with covid-19

#### Protocol summary

##### Study aim

determination of the efficiency and safety of favipiravir+hydroxychloroquine in comparison with hydroxychloroquine in hospitalized patients with covid-19

##### Design

Clinical trial with control group, double-blind, randomized, phase 3 on 50 patients. Table of random numbers are used for randomization.

##### Settings and conduct

The study is performed in the wards of Shahid Modarres Hospital. Participants, clinical care providers and evaluators of final outcomes are blinded.

##### Participants/Inclusion and exclusion criteria

Inpatients with COVID-19 in Shahid Modarres Hospital who have the conditions to enter the study: Inclusion Criteria: -Respiratory Rate(RR) $\geq$ 30 /min -SpO<sub>2</sub><93% on room air -PaO<sub>2</sub>/FIO<sub>2</sub><300 -CT scan Involvement>50% - Diagnosis confirmed by CPR or CT scan -Age more than 18 years - Obtaining the written informed consent from the patient or his/her legal guardian to participate in the clinical trial Exclusion Criteria: -G6PD Deficiency -QT interval more than 450 milliseconds -myasthenia gravis - Pregnancy- Breast Feeding -Severe Renal or Hepatic Failure

##### Intervention groups

Dosage of the drug in the intervention group: 1600 mg of Favipiravir BD on the first day, 600 mg of Favipiravir BD on the second to fifth day, and concurrent 400 mg of hydroxychloroquine BD on the first day, and 200 mg BD daily on the second to fifth day . The two groups will receive standard treatment (oxygen and, if necessary, antibiotics). Dosage of the drug in the control group: hydroxychloroquine drug 400 mg BD on the first day and 200 mg hydroxychloroquine BD daily on the second to fifth day. Increase the duration of treatment to 10 days according to the doctor's order. The control group will

receive placebo instead of Favipiravir.

##### Main outcome variables

- Discharge criteria include: no fever for 3 days, SpO<sub>2</sub>>93%, relative improvement in CXR - All cause Mortality - Need to Mechanical ventilation -Drug Adverse Effect

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200428047228N1**

Registration date: **2020-05-16, 1399/02/27**

Registration timing: **prospective**

Last update: **2020-05-16, 1399/02/27**

Update count: **0**

##### Registration date

2020-05-16, 1399/02/27

##### Registrant information

##### Name

Sanaz Zargar Balaye Jame

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4382 2959

##### Email address

sanazzargar@ajaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-19, 1399/02/30

##### Expected recruitment end date

2020-06-19, 1399/03/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the efficiency and safety of favipiravir + hydroxychloroquine drug regimen in comparison with hydroxychloroquine in hospitalized patients with covid-19

**Public title**

Evaluation of the efficiency and safety of favipiravir + hydroxychloroquine drug regimen in comparison with hydroxychloroquine in hospitalized patients with covid-19

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

a- Respiratory Rate(RR) $\geq$ 30 /min b- SpO<sub>2</sub><93% on room air c- PaO<sub>2</sub>/FIO<sub>2</sub><300 d- CT scan Involvement>50% e- Diagnosis confirmed by CPR or CT scan f- Age more than 18 years

**Exclusion criteria:**

a- G6PD Deficiency b- QT interval more than 450 milliseconds c- myasthenia gravis d- Pregnancy- Breast Feeding e- Severe Renal or Hepatic Failure

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization, Random Number Table

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants, health care personnel and evaluators of the final outcome are unaware of the drug given to the intervention and control group .

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

•Ethics committee of Shahid Beheshti University of Medical Sciences

**Street address**

shahid Modarres Hospital, Saadat Abad, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1998734383

**Approval date**

2020-04-20, 1399/02/01

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1399.053

**Health conditions studied****1****Description of health condition studied**

COVID-19

**ICD-10 code**

COVID-19

**ICD-10 code description**

U07.1 - COVID-19

**Primary outcomes****1****Description**

No fever for 3 days

**Timepoint**

Daily

**Method of measurement**

Medical Records

**2****Description**

- SpO<sub>2</sub>>93%

**Timepoint**

daily

**Method of measurement**

Medical Records

**3****Description**

CXR observation

**Timepoint**

After the end of the treatment period

**Method of measurement**

Observation

## Secondary outcomes

### 1

#### Description

- All cause Mortality

#### Timepoint

once

#### Method of measurement

Medical Records

### 2

#### Description

- Need to Mechanical ventilation

#### Timepoint

Daily

#### Method of measurement

Medical Records

### 3

#### Description

Drug Adverse Effect

#### Timepoint

Daily

#### Method of measurement

Medical Records

## Intervention groups

### 1

#### Description

Intervention group: On the first day, 1600 mg of Favipiravir BD, and on the second to fifth day, 600 mg of Favipiravir BD and concurrent hydroxychloroquine, 400 mg BD on the first day and 200 mg hydroxychloroquine BD daily on the second to fifth day. The two groups will receive standard treatment (oxygen and, if necessary, antibiotics).

#### Category

Treatment - Drugs

### 2

#### Description

Control group: hydroxychloroquine, 400 mg BD on the first day and 200 mg hydroxychloroquine BD daily on the second to fifth day. Increasing the duration of treatment to 10 days, according to the doctor's order. The control group will receive placebo instead of Favipiravir.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Modarres Hospital

#### Full name of responsible person

Dr.Mohammad Fathi

#### Street address

Shahid Modarres Hospital, Saadat Abad, Tehran, Iran

#### City

Tehran

#### Province

Tehran

#### Postal code

1998734383

#### Phone

+98 21 2351 5366

#### Email

m.fathi@sbm.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Quality Improvement of Intensive Care Research Center- Shahid Beheshti University

##### Full name of responsible person

Dr.Mohammad Fathi

##### Street address

Shahid Modarres Hospital, Saadat Abad, Tehran, Iran

##### City

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##### Province

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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

Quality Improvement of Intensive Care Research Center- Shahid Beheshti University

#### 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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Fathi

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Shahid Modarres Hospital, Saadat abad, Tehran, Iran

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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+98 21 2351 5366

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m.fathi@sbmu.ac.ir

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Fathi

**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**

Data can be shared after deleting participants' names.

**When the data will become available and for how long**

The access period will be started six months after the publication of the article.

**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.Mohammad Fathi(m.fathi@sbmu.ac.ir)

**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 Shahid beheshti university.

**Comments**