

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### A Field Trial to examine the effect of hydroxychloroquine prophylaxis in preventing the sever forms of COVID-19 infection in asymptomatic healthcare workers (A double blind placebo controlled study)

#### Protocol summary

##### Study aim

Efficacy of hydroxychloroquine in prevention of sever forms of COVID-19 Disease will be studied.

##### Design

Randomized placebo controlled field trial, 400 participants

##### Settings and conduct

This study is a double blind placebo controlled field trial on 400 participants. Using balanced blocked randomization people are randomly assigned to one of the two groups. The subjects in the intervention group will take 800 mg hydroxychloroquine tablets, ie four 200mg tablets, in two separate doses on the same day in the first week and then 400 mg, ie 2 tablets weekly in a single dose for 7 weeks. The control group will take a placebo in the same order. Tablets should be given after meal. Both groups will be followed for 10 weeks. The participants who caught COVID-19 during the study period will be followed until the end of the disease to assess the outcomes.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthcare workers and students of Islamic Azad University Tehran Medical Branch (IAUTMU) affiliated hospitals Age 18-70 y and no symptoms of COVID-19 at the time of registration Desire to participate in the study and filling out the consent form Exclusion criteria: Contraindications for hydroxychloroquine including allergy to hydroxychloroquine, G6PD, Long QT Syndrome, Porphyria, rethinopathy Acute symptoms of COVID-19 at the time of registration COVID-19 diagnosis within the past 3 months Pregnancy Sever kidney or liver disease HIV, AIDS Systemic lupus erythematosus, rheumatoid arthritis Active cancer

##### Intervention groups

Intervention Group (200 people) will get hydroxychloroquine and Control Group (200 people) will get placebo as per study protocol and will have follow-up

for 10 weeks.

##### Main outcome variables

1. Sever forms of COVID-19 needing admission to medical ward 2. ICU admission 3. mortality 4. mild forms of COVID-19

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200424047184N1**

Registration date: **2021-01-16, 1399/10/27**

Registration timing: **retrospective**

Last update: **2021-01-16, 1399/10/27**

Update count: **0**

##### Registration date

2021-01-16, 1399/10/27

##### Registrant information

##### Name

Mahnaz Valizadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5534 6210

##### Email address

valizadeh@iautmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-03, 1399/01/15

##### Expected recruitment end date

2020-10-21, 1399/07/30

**Actual recruitment start date**

2020-04-13, 1399/01/25

**Actual recruitment end date**

2020-10-21, 1399/07/30

**Trial completion date**

2020-12-30, 1399/10/10

**Scientific title**

A Field Trial to examine the effect of hydroxychloroquine prophylaxis in preventing the sever forms of COVID-19 infection in asymptomatic healthcare workers (A double blind placebo controlled study)

**Public title**

Hydroxychloroquine in prevention of sever forms of COVID-19 in healthcare workers

**Purpose**

Prevention

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

Healthcare workers and students of Islamic Azad University Tehran Medical Branch(IAUTMU) affiliated hospitals. Age 18-70 years No symptoms of COVID19 at the time of registration No history of COVID-19 diagnosis within the past 3 months from joining the study Desire to participate in the study and filling out the consent form

**Exclusion criteria:**

Any of COVID-19 symptoms at registration: fever, chills, cough, dyspnea,runny nose, loss of smell, loss of taste, headache, sore throat, chest pain, abdominal pain, nausea, vomiting, diarrhea, malaise and musculoskeletal pain History of COVID-19 within the past 3 months Contraindications for hydroxychloroquine including allergy to hydroxychloroquine , G6PD, Long QT Syndrome, porphyria, retinopathy Pregnancy Sever kidney or liver disease HIV, AIDS Systemic lupus erythematosus, rheumatoid arthritis active cancer

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **400**

Actual sample size reached: **365**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Using Balanced- Blocked Randomization, subjects are randomly assigned to one of the two control and intervention groups. The computerization process is done by an epidemiologist and a statistician. Individuals will enter the assigned groups based on their entry sequence. For the drug under study placebo is made by

the same pharmaceutical company. Participants in the study are blind to receive actual medication. People who measure variables during research are also blind about how people belong to the groups ( two way blinding).

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This study is a double blind field trial. Hydroxychloroquine and placebo are made by Tehran Darou pharmaceutical company in uniform packages with defined codes. Drug and placebo will be dispensed by a third party. The participants in the study are blind to receive actual medication. People who measure the variables and fill out the questionnaires during the research are also blind about how people belong to the groups (two way blinding).

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

Duration of the study (7 weeks of intervention and 10 weeks of follow up) is longer than the previous studies. Also the protocol of the study is different and is somehow similar to what is being used in malaria prophylaxis.

**Secondary Ids**

empty

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

Ethics committee of Islamic Azad University Tehran Medical Sciences, Faculty of pharmacy

**Street address**

No. 16, West Gholeyakh, Ayeneh Boulevard, Pabarja St. Shariati St.

**City**

Tehran

**Province**

Tehran

**Postal code**

1916893813

**Approval date**

2020-04-12, 1399/01/24

**Ethics committee reference number**

IR.IAU.PS.REC.1399.001

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

COVID-19

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID19, virus identified

## Primary outcomes

### 1

#### Description

Sever forms of COVID-19( sever dyspnea, chest pain, decreased level of consciousness based on CDC definition) needing admission to hospital

#### Timepoint

Weekly for 10 weeks or until the discharge from hospital whichever is longer

#### Method of measurement

Weekly phone calls to participants and filling out the questionnaire forms

### 2

#### Description

Sever forms of COVID-19 Diseases needing admission to ICU due to respiratory failure

#### Timepoint

Weekly for 10 weeks or until the discharge from hospital whichever is longer

#### Method of measurement

Weekly phone calls to participants and filling out the questionnaire forms

### 3

#### Description

Mortality

#### Timepoint

weekly for 10 weeks or until discharge from hospital whichever is longer

#### Method of measurement

Weekly phone calls to participants and filling out the questionnaire forms

### 4

#### Description

Mild types of COVID-19 with at least one of the symptoms of fever, cough, dyspnea, myalgia, loss of smell or taste, flu like symptoms with either polymerase-chain-reaction (PCR) confirmed COVID-19 or Positive CT scan suggestive of COVID-19.

#### Timepoint

Weekly for 10 weeks

#### Method of measurement

Weekly phone calls to participants and filling out the questionnaire forms

## Secondary outcomes

### 1

#### Description

drug side effect

#### Timepoint

weekly for 7 weeks

#### Method of measurement

Weekly phone calls and filling out the questionnaire

forms

## Intervention groups

### 1

#### Description

Intervention group: The intervention group will take 800 mg i.e four 200 mg tablets of hydroxychloroquine in two separate doses once; and then 400 mg weekly in a single dose for 7 weeks and will be followed-up for 10 weeks. Drug and placebo are made by Tehran Darou Pharmaceutical Company.

#### Category

Prevention

### 2

#### Description

Control group: Control group will take four placebo tablets in two separate doses once and then two placebo tablets weekly in a single dose for 7 weeks. They will be followed-up for 10 weeks. Drug and placebo are made by Tehran Darou Pharmaceutical Company.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amir al Momenin Javadieh Hospital

##### Full name of responsible person

DR. Mahnaz Valizadeh

##### Street address

Research Room, Amir al momenin Javadieh hospital, ShirMohammadi St. Naziabad

##### City

Tehran

##### Province

Tehran

##### Postal code

1811694784

##### Phone

+98 21 5534 6210

##### Email

valizadeh@iautmu.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Farhikhtegan Hospital

##### Full name of responsible person

Fatemeh Zareei

##### Street address

Satari North, Daneshgah square, Farhikhtegan Hospital

##### City

Tehran

**Province**  
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**Postal code**  
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**Phone**  
+98 21 4486 7262  
**Email**  
midwiferysaveh@gmail.com

### 3

**Recruitment center**  
**Name of recruitment center**  
Bu Ali Hospital  
**Full name of responsible person**  
Zahra Eskandari  
**Street address**  
Bu Ali Hospital, Damavand St., Imam Hossein Square  
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**Province**  
Tehran  
**Postal code**  
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valizadehmahnaz@yahoo.com

### 4

**Recruitment center**  
**Name of recruitment center**  
Shayan Clinic ( Day surgery Clinic)  
**Full name of responsible person**  
Massoud Bonyadi  
**Street address**  
No 192, Shayan Clinic, Mirdamad Boulevard  
**City**  
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**Province**  
Tehran  
**Postal code**  
1549634616  
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**Email**  
drbonyadi@gmail.com

### 5

**Recruitment center**  
**Name of recruitment center**  
Mirdamad Clinic ( Day surgery Clinic)  
**Full name of responsible person**  
Dr. Massoud Bonyadi  
**Street address**  
No. 367, Mirdamad Clinic, Mirdamad Boulevard  
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**Postal code**

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**Phone**  
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**Email**  
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### 6

**Recruitment center**  
**Name of recruitment center**  
Baharan clinic (out patient clinic)  
**Full name of responsible person**  
Dr. Mahnaz Valizadeh  
**Street address**  
5th floor, No 60, Manzarnejad St. Shariati St.  
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valizadehmahnaz@yahoo.com

## **Sponsors / Funding sources**

### 1

**Sponsor**  
**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
DR. Majid Naghipour  
**Street address**  
No16, Gholeyakh, Ayeneh boulevard, Pabarja St, Shariati St. (Deputy of Research office)  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1916893813  
**Phone**  
+98 21 2264 0599  
**Email**  
naghipour@iautmu.ac.ir

**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Islamic Azad University  
**Proportion provided by this source**  
100  
**Public or private sector**  
Private  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

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**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Mahnaz Valizadeh

**Position**

Assistant Professor on Internal Medicine

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

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**Person responsible for updating data**

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**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Mahnaz Valizadeh

**Position**

Assistant Professor of Internal Medicine

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

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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