

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)

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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 severe forms of COVID-19 infection in asymptomatic healthcare workers (A double blind placebo controlled study)

Public title

Hydroxychloroquine in prevention of severe 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 COVID-19 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 Severe 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

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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

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2

Recruitment center

Name of recruitment center

Farhikhtegan Hospital

Full name of responsible person

Fatemeh Zareei

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3

Recruitment center
Name of recruitment center
Bu Ali Hospital
Full name of responsible person
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4

Recruitment center
Name of recruitment center
Shayan Clinic (Day surgery Clinic)
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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6

Recruitment center
Name of recruitment center
Baharan clinic (out patient clinic)
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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No16, Gholeyakh, Ayeneh boulevard, Pabarja St, Shariati St. (Deputy of Research office)
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Postal code
1916893813
Phone
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Email
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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
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

Phone

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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

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Other areas of specialty/work

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Street address

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Province

Tehran

Postal code

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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