Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A Community Trial to examine the effect of hydroxychloroquine prophylaxis in preventing the sever forms of Covid-19 in asymptomatic people

Protocol summary

Study aim
The effect of prophylaxis treatment with hydroxychloroquine on the incidence of severe forms of covid-19 virus

Design
Randomized controlled trial study; double-blind; parallel groups; on 1000 people; randomization using balanced blocks

Settings and conduct
Using balanced blocked randomization people are randomly assigned to one of the two control and intervention groups. The computerization process is done by an epidemiologist and a statistician. For the drug under study, placebo is made by a pharmaceutical company, and participants in the study are blind to receive actual medication. People who measure variables during research are also blind about how people belong to groups. (Two-way blinding) Both intervention and control groups are followed for 10 weeks.

Participants/Inclusion and exclusion criteria
Men and women 65-18 years wish to participate in the study have no suspicious symptoms of covid-19 disease Do not have positive test

Intervention groups
Intervention Group is500 people and Control Group is 500 people and they are under intervention and follow-up for 10 weeks.

Main outcome variables
- COVID-19 Mild type (fever - cough - shortness of breath and positive PCR test) - severe (severe dyspnea - chest pain or constant pressure - decreased level of consciousness - bruising of lips and face and positive PCR test) based on CDC definition

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200421047153N1**
Registration date: **2020-12-19, 1399/09/29**
Registration timing: **retrospective**

Last update: **2020-12-19, 1399/09/29**
Update count: **0**

Registration date
2020-12-19, 1399/09/29

Registrant information

Name
Termeh Tarjoman

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 5534 6262

Email address
t.tarjoman@iautmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-04, 1399/04/14

Expected recruitment end date
2020-12-05, 1399/09/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A Community Trial to examine the effect of

hydroxychloroquine prophylaxis in preventing the sever forms of Covid-19 in asymptomatic people

Public title
Hydroxychloroquine prophylaxis in preventing the severe forms of Covid-19
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
18-65 years old No symptoms of corona and no positive corona test The desire to participate in the study No symptoms of disease at the time of admission No positive test
Exclusion criteria:
History of allergy to hydroxychloroquine Contraindications for drug use include previous history of retinopathy or G6PD, LONG QT SYNDROME, porphyry Positive HIV patients Patients with autoimmune diseases (lupus-rheumatoid arthritis) BMI >40 Diabetic CKD Using medications with contraindication to use hydroxychloroquine
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **1000**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation will be used in this trial based on balance block randomization and by 4:1 blocks. The randomization table was designed by the epidemiologist for a sample size of 1000 people according to the two study arms A and B (intervention and placebo). The balanced blocks were selectively four so, A and B were repeated in these blocks. The codes listed in the table from 1 to 1000 are unique to each participant. At the time of performance by referring to this list,a package of 10 pills (medicine or placebo) coded by a pharmaceutical expert is given to the person . The software used is SPSS18.
Blinding (investigator's opinion)
Double blinded
Blinding description
Individuals are divided in groups A or B according to the prepared sequence . The codes listed in the table are unique to each participant . After completing, the sequence will be given to the manufacturer of the drug and placebo . The company puts drugs and placebo into envelopes according to each person's code and provides the researcher with a label of person's code written on them.Therefore, participant and who will assess patients in follow-up visits will be unaware of each number belongs to which groups(A or B).
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Azad University of Medical Sciences I Scien ces
Street address
No16,west Goleyakh Ave.Gholhak Ave,Shariati
City
Tehran
Province
Tehran
Postal code
1946614733
Approval date
2020-04-09, 1399/01/21
Ethics committee reference number
IR.IAU.PS.REC.1399.003

Health conditions studied

1

Description of health condition studied
Covid-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
incidence of mild type covid-19 (fever - cough - dyspnea-positive PCRtest)-CDC
Timepoint
weekly for 10 weeks
Method of measurement
phone interview -medical record review

2

Description
incidence of severe type (dyspnea - chest pain or pressure - decreased level of consciousness - bruising of the lips and face and positive PCR test) based on CDC definition

Timepoint
weekly for 10 weeks
Method of measurement
phone interview -medical record review

Secondary outcomes

1

Description
hospitalization need
Timepoint
Weekly to 10 weeks
Method of measurement
phone interview -medical record review

2

Description
mechanical ventilation need
Timepoint
Weekly to 10 weeks
Method of measurement
phone interview -medical record review

3

Description
Deaths
Timepoint
Weekly to 10 weeks
Method of measurement
phone interview -medical record review

Intervention groups

1

Description
Intervention group (500 individuals): 800 mg hydroxychlorine tablet i two separate doses daily for one week and then 200 mg tablet daily for 6 weeks
Category
Prevention

2

Description
Control group: 500 people placebo group 800 mg placebo tablet in two separate doses daily for one week and then 200 mg tablet daily for 6 weeks
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir-Al -Momenin hospital
Full name of responsible person
Termeh Tarjoman
Street address
Amir-Al -Momenin hospital- Shirmohammadi Ave- Naziabad
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1811694784
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Farshad Hashemian
Street address
Amir-al-momenin hospital-Shirmohammadi Ave- Naziabad
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Islamic Azad University of Medical Sciences
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
Islamic Azad University
Full name of responsible person

Termeh Tarjoman

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Public Health/Community Medicine

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Amir-al-momenin hospital- Shirmohammadi Ave-Naziabad

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Person responsible for updating data

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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
No - There is not 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
Not applicable

Data Dictionary
Not applicable