

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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 is 500 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 severe forms of Covid-19 in asymptomatic people		belongs to which groups(A or B).	
Public title	Hydroxychloroquine prophylaxis in preventing the severe forms of Covid-19	Placebo	Used
Purpose	Prevention	Assignment	Parallel
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	Other design features	
Age	From 18 years old to 65 years old	Secondary Ids	
Gender	Both	empty	
Phase	3	Ethics committees	
Groups that have been masked	- Participant - Investigator - Outcome assessor	1	
Sample size	Target sample size: 1000	Ethics committee	
Randomization (investigator's opinion)	Randomized	Name of ethics committee	
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.	Ethics committee of Azad University of Medical Sciences I Scien ces	
Blinding (investigator's opinion)	Double blinded	Street address	
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	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

Phone

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Email

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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-
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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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Person responsible for scientific inquiries

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Name of organization / entity

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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