

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Prevention of COVID-19 disease after contact with an infected patient with coronavirus after taking hydroxychloroquine in the community

#### Protocol summary

##### Study aim

Reducing the incidence of the COVID-19 disease and reducing the hospitalization by taking hydroxychloroquine drug

##### Design

Clinical trial with control group, with parallel, and randomized groups

##### Settings and conduct

This study is performed on people who came in close contact with infected patients with COVID-19 who were admitted to medical centers affiliated with Iran University of Medical Sciences. This study is a randomized clinical trial with parallel groups which is done under the supervision of trained nursing experts located in the Endocrine Research Institute of Iran University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: People over the age of 40 who have been in contact with a person with COVID-19 disease  
Exclusion Criteria: Pregnancy; Enzymatic disorders caused by certain drugs result in red blood cell lysis (G6PD) ; The history of Retinopathy; Cardiac Arrhythmia

##### Intervention groups

Experimental group( taking hydroxychloroquine ) and Control group

##### Main outcome variables

Reducing the incidence of COVID-19; Reducing the hospitalization time in Medical Center ; Decreasing the number of acute symptomatic respiratory patients; Reducing the number of patients with COVID-19

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190122042450N4**

Registration date: **2020-04-16, 1399/01/28**

Registration timing: **prospective**

Last update: **2020-04-16, 1399/01/28**

Update count: **0**

##### Registration date

2020-04-16, 1399/01/28

##### Registrant information

###### Name

Mohammad Ebrahim Khamseh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8894 5246

###### Email address

khamseh.m@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-20, 1399/02/01

##### Expected recruitment end date

2020-06-20, 1399/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Prevention of COVID-19 disease after contact with an infected patient with coronavirus after taking hydroxychloroquine in the community

##### Public title

The effect of hydroxychloroquine to prevent coronavirus disease

##### Purpose

Health service research

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Clinical symptoms including: Fever Shortness of breath  
Cough Positive Covide test Typical symptoms on a CT scan

**Exclusion criteria:**

Hypersensitivity reaction to Hydroxychloroquine Already taking Chloroquine or Hydroxychloroquine Cardiac Arrhythmia Already taking drugs that prolong QT Decreased renal function in stages 4 and 5.(GFR <30) The history of enzymatic disorders caused by some drugs that result in red blood cell lysis (G6PD). The history of Retinopathy Pregnancy

**Age**

From **40 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **1000**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is done using random block method with variable block size. In this method, a number is randomly selected from the numbers 2, 4, 6, and 8. Then, according to the size of the selected block, a random combination of 2 studied treatments is selected. This process is repeated to the extent that a sequence of 1000 of 1 and 2 treatments is created, provided that the number of each of the two treatments is 500. At the time of performance, for each patient, by referring to this list, it is decided which of the two treatments to be assigned to him.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics committee of Iran University of Medical Sciences

**Street address**

Hemmat Highway. Next to Milad Tower

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۴۹۶۱۴۵۳۵

**Approval date**

2020-04-11, 1399/01/23

**Ethics committee reference number**

IR.IUMS.REC.1399.076

**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**

Reduction of incubation time

**Timepoint**

Daily for 14 days

**Method of measurement**

Participants' clinical status

**2****Description**

Reducing the incidence of Symptomatic respiratory disease

**Timepoint**

14 days after taking hydroxychloroquine

**Method of measurement**

CT-scan test

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: hydroxychloroquine Ruzdarou 200mg; This group take 2 hydroxychloroquine tablet (400 mg) for the first day and From the second day, take one tablet (200 mg) daily for two weeks.

**Category**

Prevention

**2****Description**

Control group: Domestic quarantine for 14 days

**Category**

Prevention

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Hospitals of Iran University of Medical Science

**Full name of responsible person**

Mohammad Ebrahim Khamseh

**Street address**

Firouzeh Street

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## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr. Abbas Motavallian

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Hemmat Highway

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<https://iums.ac.ir/fa?sid=120>

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran 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**

The Institute of Endocrinology and Metabolism  
Research and Training Center

**Full name of responsible person**

Mohammad Ebrahim Khamseh

**Position**

The head of Institute

**Latest degree**

Subspecialist

**Other areas of specialty/work**

glandulae endocrinae

**Street address**

Firoozeh Alley, Vali-asr Sq, Tehran, Iran

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

The Institute of Endocrinology and Metabolism  
Research and Training Center

**Full name of responsible person**

Mohammad Ebrahim Khamseh

**Position**

The Head of Institute

**Latest degree**

Subspecialist

**Other areas of specialty/work**

glandulae endocrinae

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## Person responsible for updating data

**Contact****Name of organization / entity**

The Institute of Endocrinology and Metabolism  
Research and Training Center

**Full name of responsible person**

Fereshteh Abdolmaleki

**Position**

Research Assistance

**Latest degree**

Master

**Other areas of specialty/work**

Medical Biotechnology

**Street address**

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**Postal code**

1593716615

**Phone**

## 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