

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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

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Postal code
۱۳۴۹۶۱۴۵۳۵
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

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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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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

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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

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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

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