Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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
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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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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
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Person responsible for scientific inquiries

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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