

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation the efficacy and safety of Hydroxychloroquine administration for COVID-19 post exposure prophylaxis

Protocol summary

Study aim

Evaluation the efficacy and safety of Hydroxychloroquine administration for COVID-19 post exposure prophylaxis

Design

Randomized clinical trial with control group

Settings and conduct

Loghman Hakim Hospital

Participants/Inclusion and exclusion criteria

In this study, patients who are over 18 years old and had a close contact with a COVID-19 case at least in past 4 days and signed the informed consent form included. Also, previous cases of COVID-19 and who had flu like symptoms or those with travel history excluded.

Intervention groups

In intervention group, participants receive Hydroxychloroquine (Amin Pharmaceutical company, Isfahan) at dose of 200 mg TDS up to 7 days. In control group, participants receive no medicines. At first of study and at 7 days later, nasopharyngeal specimen will be collect to detect COVID-19.

Main outcome variables

Fever; cough; dyspnea; get infected with COVID-19; death

General information

Reason for update

Acronym

HOPEC

IRCT registration information

IRCT registration number: **IRCT20130917014693N10**

Registration date: **2020-04-08, 1399/01/20**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-08, 1399/01/20**

Update count: **0**

Registration date

2020-04-08, 1399/01/20

Registrant information

Name

Zahra Sahraei

Name of organization / entity

Faculty of pharmacy, Shahid beheshti university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8887 3704

Email address

z.sahraei@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-07, 1399/01/19

Expected recruitment end date

2020-06-08, 1399/03/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the efficacy and safety of Hydroxychloroquine administration for COVID-19 post exposure prophylaxis

Public title

Evaluation the effects of Hydroxychloroquine administration for COVID-19 prophylaxis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years old Close contact with COVID-19 patient at least in past 4 days sign the informed consent form to participate in study

Exclusion criteria:

Pervious case of COVID-19
Current case of COVID-19
Presenting influenza like symptoms (fever, cough, and sore throat) in last 30 days
Travel history in last 14 days
Lactation and pregnancy
History of arrhythmia
Drug allergy history
Favism history
Chronic liver disease
Chronic kidney disease
Retinopathy history
Weight under 40 kg
Patients who are receiving arritmogenica medicines

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, simple randomization method will be used. A randomized list will be generated by online randomization site. Households will be allocated to case or control group according to the generated list. Then cluster sampling will be done in each group.

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**

Vice-Chancellor in Research Affairs - Shahid Beheshti
University of Medical Sciences

Street address

3 rd floor, School of Medicine, Evin St, Shahid
Chamran Highway

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2020-04-06, 1399/01/18

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.026

Health conditions studied**1****Description of health condition studied**

COVID-19 pneumonia

ICD-10 code

U07.2

ICD-10 code description

COVID-19, virus not identified

Primary outcomes**1****Description**

Fever

Timepoint

Daily

Method of measurement

Thermometer

2**Description**

Cough

Timepoint

Daily

Method of measurement

Questionnaire

3**Description**

Dyspnea

Timepoint

Daily

Method of measurement

Questionnaire

4**Description**

Sore throat

Timepoint

Daily

Method of measurement

Questionnaire

5**Description**

Myalgia

Timepoint

Daily

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Disease severity

Timepoint

At end of the study

Method of measurement

Clinical scoring for disease severity

2

Description

Death

Timepoint

Day 7, day 14, and day 28

Method of measurement

Observation

3

Description

Adverse reactions

Timepoint

Daily

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: Participants receive Hydroxychloroquine (Amin Pharmaceutical company, Isfahan) at dose of 200 mg TDS up to 7 days.

Category

Prevention

2

Description

Control group: Participants receive no medicines.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim Hospital

Full name of responsible person

Minoosh Shabani

Street address

Loghman Hakim Hospital, Kamali St, Makhsoos St

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1333635445

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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3 rd floor, School of Medicine, Evin St, Shahid Chamran Highway

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Omidvar Rezaeimirghaed

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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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)

Yes - There is 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

Not applicable

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

Title and more details about the data/document

All potential data can be shared after blinding

When the data will become available and for how long

Six months after results published

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

For research purposes and further analysis

From where data/document is obtainable

Dr. Zahra Sahraei, Loghman Hakim Hospital, Kamali St, Makhsoos St, Tehran

What processes are involved for a request to access data/document

Official letter to the researchers

Comments