

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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, pervious 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1333635445

##### Phone

+98 21 5541 9005

##### Email

meinoosh53@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Afshin Zarghi

##### Street address

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

##### City

Tehran

##### Province

Tehran

##### Postal code

1983963113

##### Phone

+98 21 23871

##### Email

mpd@sbm.ac.ir

##### 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

##### Street address

Loghman Hakim Hospital, Kamali St, Makhsoos St

##### City

Tehran

**Province**

Tehran

**Postal code**

1333635445

**Phone**

+98 21 5541 9005

**Email**

alisaffaei.ss@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Zahra Sahraei

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**Valieasr St, Niyayesh Highway, Shahid Beheshti  
University of Medical Sciences, School of Pharmacy**City**

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**Province**

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**Postal code**

1991953381

**Phone**

+98 21 8820 0118

**Email**

zahra.sahraei@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Ali Saffaei

**Position**

Clinical Pharmacy Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

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+98 21 8820 0118

**Email**

alisaffaei.ss@gmail.com

**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,  
Makhsos St, Tehran**What processes are involved for a request to access data/document**

Official letter to the researchers

**Comments**