# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

23 Feb 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)
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+98 21 8887 3704
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**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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## 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 Rezaiemirghaed
**Position**
Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Neurosurgery
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## Person responsible for scientific inquiries

**Contact**
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## Person responsible for updating data

**Contact**
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Ali Saffaei
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**Latest degree**
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**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 mounts 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**