Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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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
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Loghman Hakim Hospital, Kamali St, Makhsoos St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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Position
Professor
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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 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