

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The prophylactic effect of oral hydroxy-chloroquine in close contacts of COVID-19 patients

#### Protocol summary

The prophylactic effect of oral hydroxy-chloroquine in close contacts of COVID-19 patients

#### Study aim

Evaluation of the preventive effect of oral administration of hydroxychloroquine tablets in people who were in close contact with patients with COVID-19 disease hospitalized in Bushehr hospitals.

#### Design

Study group: Cases of this group are treated with preventive treatment of hydroxychloroquine as follows. The control group also uses vitamin B1 tablets, which, in terms of drug form, color and odor, are similar to hydroxychloroquine.

#### Settings and conduct

After obtaining the consent of the person, he will undergo a clinical trial. In this phase, the clinical trial performer has no knowledge of type of pills(drugs) given to individuals, as well as the individuals themselves, whether they are hydroxychloroquine or a placebo.

#### Participants/Inclusion and exclusion criteria

Close contact with a person with COVID-19 who has been diagnosed positive with a definitive test.

#### Intervention groups

After obtaining the consent of the person, he will undergo a clinical trial. In this phase, the clinical trial performer has no knowledge of type of pills(drugs) given to individuals, as well as the individuals themselves, whether they are hydroxychloroquine or a placebo. Control group: The cases of this group are treated with preventive treatment of placebo for 6 days, which are used orally once a day at 22:00. Study group: Cases of this group are treated with preventive treatment of hydroxychloroquine as follows. 1-hydroxychloroquine 400 mg tablet once on the first night at 22:00 2-hydroxychloroquine 200 mg tablet once a night for 5 nights at 22:00 It should be noted that patients will be monitored directly to prevent the effects of disruptive factors. The control group also uses vitamin B1 tablets, which, in terms of drug form, color and odor, are similar to hydroxychloroquine.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

COVID

##### IRCT registration information

IRCT registration number: **IRCT20200513047426N1**

Registration date: **2020-06-27, 1399/04/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-06-27, 1399/04/07**

Update count: **0**

##### Registration date

2020-06-27, 1399/04/07

##### Registrant information

##### Name

Ramin Rezaee

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 77 3424 5286

##### Email address

drrezaee.ramin@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-21, 1399/04/01

##### Expected recruitment end date

2020-07-22, 1399/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The prophylactic effect of oral hydroxy-chloroquine in close contacts of COVID-19 patients

**Public title**  
The prophylactic effect of oral hydroxy-chloroquine in close contacts of COVID-19 patients

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Close contact with a person with COVID-19 who has been diagnosed positive with a definitive test. Close contact: contact, hand shake and talking at least once in the last 2 days for less than 2 meters with COVID-19 patient who have been diagnosed positive with a definitive test. Family, friends, relatives who have been in the same place for a period of 4 hours or more in the last 2 days with a COVID-19 patient who have been diagnosed with a definitive test. Medical staff, including physicians, nurses, midwives, and service personnel which have been in contact with COVID-19 patient who has been diagnosed with a definitive test in the past three days.  
**Exclusion criteria:**  
Lack of satisfaction from entered persons The presence of diseases or conditions in which the use of hydroxychloroquine is as a contraindication, such as patients with heart failure who take QT prolonging drugs are as contraindications. Existence of distorting factors during the implementation of clinical trial.+ During the study, people should be in home quarantine. + Do not Excessive use of vitamins and medications.+ has Meals like family's.+has Regular sleep cycle Complications of hydroxychloroquine based on the Iranian rheumatology association include the following:1- Nausea, decreased appetite and diarrhea 2- Skin allergies 3- Skin discoloration 4- Ocular sensitivity 5- Headache 6- Rash

**Age**  
No age limit

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **500**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Close contact with a person with COVID-19 who has been diagnosed positive with a definitive test can be known.sample size can be measured by following

formula:  $F = (P_1 + P_2) / 2$   $n = (z_{(1-\alpha/2)} \sqrt{2P(1-P)} + z_{(1-\beta)} \sqrt{P_1(1-P_1) + P_2(1-P_2)}) / (P_1 - P_2)^2$  sample size=500 person Restricted randomization by Random allocation rule

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Participants, main researchers, health care personnel (physicians, nurses, students, etc.) who are responsible for patients care, data collection, and those who evaluate the outcome. Of course, the patient is informed consciously, but is not aware of the nature of the medication he is taking, and assumes that all participants are taking the same medication.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Boshehe University of Medical Sciences

##### Street address

Moallem Ave

##### City

Boshehr

##### Province

Boushehr

##### Postal code

7518759577

#### Approval date

2020-04-05, 1399/01/17

#### Ethics committee reference number

IR.BPUMS.REC.1399.017

## Health conditions studied

### 1

#### Description of health condition studied

Covid19

#### ICD-10 code

B34.2

#### ICD-10 code description

Coronavirus infection, unspecified

## Primary outcomes

### 1

#### Description

Percentage of people who have not been diagnosed with

Covid19 after co-administration of hydroxychloroquine.

### Timepoint

The end of study

### Method of measurement

Diagnostic COVID-19 Kits

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Cases of this group are treated with preventive treatment of hydroxychloroquine as follows.1- hydroxychloroquine 400 mg tablet once on the first night at 22:00- hydroxychloroquine 200 mg tablet once a night for 5 nights at 22:00It should be noted that patients will be monitored directly to prevent the effects of disruptive factors.

#### Category

Prevention

### 2

#### Description

Control group: The cases of this group are treated with preventive treatment of placebo for 6 days, which are used orally once a day at 22:00.The control group also uses vitamin B1 tablets, which, in terms of drug form, color and odor, are similar to hydroxychloroquine.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Persian gulf hospital

##### Full name of responsible person

Dr.Ramin Rezaee

##### Street address

Moallem Ave

##### City

Boshehr

##### Province

Boshehr

##### Postal code

7518759577

##### Phone

+98 77 3345 0235

##### Email

Drrezaee.ramin@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Boshehr University of Medical Sciences

##### Full name of responsible person

Vice chancellery for research and technology

##### Street address

Moallem Ave

##### City

Boshehr

##### Province

Boshehr

##### Postal code

7518759577

##### Phone

+98 77 3345 2227

##### Email

Drrezaee.ramin@yahoo.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Boshehr 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

Boshehr University of Medical Sciences

##### Full name of responsible person

Ramin Rezaee

##### Position

Consultant

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Rheumatology

##### Street address

Moallem Ave

##### City

Boshehr

##### Province

Boshehr

##### Postal code

7518759577

##### Phone

+98 77 3345 2227

##### Email

Drrezaee.ramin@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Boushehr University of Medical Sciences

**Full name of responsible person**

Dr.Ramin Rezaee

**Position**

Consultant

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Rheumatology

**Street address**

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**City**

Boshehr

**Province**

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7518759577

**Phone**

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**Email**

Drrezaee.ramin@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Boushehr University of Medical Sciences

**Full name of responsible person**

Dr.Ramin Rezaee

**Position**

Consultant

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Rheumatology

**Street address**

Moallem Ave

**City**

Boshehr

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

not

**When the data will become available and for how long**

not

**To whom data/document is available**

not

**Under which criteria data/document could be used**

not

**From where data/document is obtainable**

not

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

not

**Comments**