Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Oct 2020

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

Protocol summary

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

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

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- Rush

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: $\bar{P}=(P_1+P_2)/2$ $n=(z_{(1-\alpha/2)} \sqrt{(2\bar{P}(1-\bar{P}))}+z_{(1-\beta)} \sqrt{(P_1 (1-P_1)+P_2 (1-P_2))})/(P_1-P_2)^2$ 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 22:002- 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

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Moallem Ave

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Phone

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Email

Drrezaee.ramin@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Vice chancellery for research and technology

Street address

Moallem Ave

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Boshehr

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Postal code

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Phone

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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

Boushehr 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

Boushehr University of Medical Sciences

Full name of responsible person

Ramin Rezaee

Position

Consultant

Latest degree

Subspecialist

Other areas of specialty/work

Rheumatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Dr.Ramin Rezaee

Position
Consultant

Latest degree
Subspecialist

Other areas of specialty/work
Rheumatology

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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
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