

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Effect of hydroxychloroquine on prevention of covid-19 virus infection among treatment staff in Arash hospital-A double-blind clinical trial

Protocol summary

Study aim

Comparison of the effect of hydroxychloroquine with placebo on prevention of virus Covid-19 in Arash hospital treatment staffs

Design

A randomized controlled clinical trial with parallel, double-blind, randomized groups

Settings and conduct

Arash hospital treatment staffs will be invited to participate in the study. After being assessed for inclusion and exclusion criteria and obtaining their consent, Participants Arash Hospital treatment staff will be invited to participate in the study. They will be enrolled in the study based on inclusion and exclusion criteria and after obtaining informed consent, they will be randomized into two groups, A and B. One group of participants will be given 400 mg hydroxychloroquine twice weekly for 3 months and the other group will be given placebo. Then, in the event of clinical signs of suspected viral infection, Covid-19 tests will be carried out based on the national protocols.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Staffs who are in contact with patients, including nurse, physician, midwife and caregiver who have at least 3 shift a week in the hospital and consent to participate in the study. Exclusion criteria: History of coronavirus infection or clinical symptoms such as fever, nausea, dispenea and myalgia in the past two months, history of underlying diseases, hypersensitivity to hydroxychloroquine, G6PD enzyme deficiency.

Intervention groups

Participants will be randomly assigned to either A or B groups and will be assigned to one hydroxychloroquine group and one placebo group.

Main outcome variables

Covid-19 virus infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120826010664N6**

Registration date: **2020-04-05, 1399/01/17**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-05, 1399/01/17**

Update count: **0**

Registration date

2020-04-05, 1399/01/17

Registrant information

Name

Reihaneh Pirjani

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7788 3288

Email address

pirjani@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-29, 1399/01/10

Expected recruitment end date

2020-06-30, 1399/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of hydroxychloroquine on prevention of covid-19 virus infection among treatment staff in Arash hospital-A double-blind clinical trial

Public title

Effect of hydroxychloroquine on prevention of covid-19 virus

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Treatment staff who are in contact with patients who have at least 3 shift a week in the hospital consent to participate in the study.

Exclusion criteria:

History of covid-19 virus infection clinical symptoms such as fever, nausea, dispenea and myalgia in the past two months history of underlying diseases hypersensitivity to hydroxychloroquine G6PD enzyme deficiency

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

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

Sample size

Target sample size: **310**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomized block allocation method was developed using Stata version 15 software by an epidemiologist. The block size was six. Allocation to treatment groups was conducted by an independent researcher (The epidemiologist). To conceal the process of random assignment, it is written on paper labels (random 10-digit codes) with no sequences and no specific framework that identifies the relevant treatment number and only the methodologist will be aware of the code. The labels will be attached to the drug packages in order of randomization. Drug packages will be arranged in a box according randomization list. When the physician declares a patient eligible, the methodologist will give him or her drug package. The person evaluating the outcomes is a third party who is unaware of the random allocation process and the type of treatment performed. The data will be analyzed by a statistician who is separate from the study process and unaware of all the processes performed.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug and placebo, which have similar size, color, taste, and odor, are provided in completely similar

containers by random assignment to both groups, so no patients will be informed of the specific treatment. The researcher is also unaware of the implications of the random allocation process and the type of treatment performed. The data will be analyzed by a statistical expert who is separate from the study process and unaware of all the processes performed.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Arash hospital, Baghdarnia st., Sardar Soleimani st,

City

Tehran

Province

Tehran

Postal code

1653915911

Approval date

2020-03-19, 1398/12/29

Ethics committee reference number

IR.TUMS.VCR.REC.1399.001

Health conditions studied**1****Description of health condition studied**

Covid-19 prophylaxis

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

covid-19 infection

Timepoint

One, two and three months after starting the drug

Method of measurement

Covid-19 PCR test and clinical symptoms

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Hydroxychloroquine 200 mg tablet of Amin Pharmaceutical, 400 mg daily and once a week for one to three months. (Based on the duration of corona virus epidemic).

Category

Prevention

2

Description

Control group: placebo which is completely similar in form and taste to 200 mg hydroxychloroquine tablet and is manufactured by the same factory (Amin Pharmacy) is given. The dosage is two tablets daily, once a week for one to three months (based on duration of Corona virus epidemic in Tehran).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash hospital

Full name of responsible person

Reihaneh Pirjani

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Arash hospital, Baghdarnia st., Sardar Soleimani st.,

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pirjani@razi.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Sixth floor. No. 226, Qods St., Keshavarz Blvd.,

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1417653761

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vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Reihaneh Pirjani MD.

Position

Perinatologist, Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Reihaneh Pirjani MD.

Position

Perinatologist, Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Reihaneh Pirjani MD.

Position

Perinatologist, Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not 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

Not applicable

Data Dictionary

Not applicable