Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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)

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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 tablet 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
Street address
Arash hospital, Baghdarnia st., Sardar Soleimani st,.
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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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Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3685
Email
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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Arash Hospital, Baghdarnia Street, Farjam Street, Tehranpars , Tehran
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Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
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Reihaneh Pirjani MD.
Position

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Person responsible for updating data

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Web page 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