Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

Evaluate the efficacy of hydroxychloroquine in the prevention of SARS-COV2 infection in high risk health care workers

Protocol summary

Study aim
The comparisson of the prevalence and the severity of COVID-19 in staff with encounter to the COVID patients in the case and control groups

Design
Two arm parallel-group phase-2 clinical trial with outcome assessment in 320 volunteer staff who encounter with COVID-19 patients divided into case group(use 400 mg/week hydroxychloroquine as prophylaxis) and control group (without any drug)

Settings and conduct
In this study, the staff of Seyedoshohada, Isabnemaryam, Khorshid, and Amin hospitals in Isfahan city who are an encounter with COVID-19 patients divided into the case (weekly use of Hydroxychrolokin for 3 months) or control(without any drugs) groups and follow-up during 6 months. The prevalence of affection or the severity of illness will be compared in the two groups.

Participants/Inclusion and exclusion criteria
Exclusion Criteria 1- Treatment with other antiviral drugs at the same time, except for the drugs prescribed in the national protocol 2 - Concomitant diseases: malignancy, advanced heart failure, cirrhosis, people under dialysis, stroke, Alzheimer's, progressive chronic neurological diseases 3- Evidence of multiorgan failure 4- Pregnancy or lactation

Intervention groups
Case group: the volunteer staff encounter with COVID-19 patients who use the hydroxychloroquine as prophylaxis in the dose of 400 milligrams per week for 3 months Control group: The staff who encounter with COVID-19 patients without any prophylaxis treatment

Main outcome variables
prevalence of COVID-19 onset; the severity of COVID-19

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200414047076N1**
Registration date: **2020-08-01, 1399/05/11**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-01, 1399/05/11**
Update count: **0**

Registration date
2020-08-01, 1399/05/11

Registrant information

Name
Elahe Nasri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3792 8006

Email address
elahe.nasri@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-18, 1399/01/30

Expected recruitment end date
2020-09-20, 1399/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluate the efficacy of hydroxychloroquine in the prevention of SARS-COV2 infection in high risk health care workers

Public title
Evaluate the efficacy of hydroxychloroquine in the prevention of SARS-COV2 infection in high risk health care workers
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Signing the consent form of high-risk personnel and exposed to the virus
Exclusion criteria:
Treatment with other antiviral drugs at the same time, except for the drugs prescribed in the national protocol Concomitant diseases: malignancy, advanced heart failure, cirrhosis, people under dialysis, stroke, Alzheimer's, progressive chronic neurological diseases Evidence of multi-organ failure Pregnancy or lactation
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **160**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Research Chancelor, Isfahan University of Medical Sciences, Hezarjerib street, Isfahan
City
Isfahan
Province
Isfehan
Postal code
81745319
Approval date
2020-03-29, 1399/01/10
Ethics committee reference number
IR.MUI.MED.REC.1399.0.17

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
covid-19

Primary outcomes

1

Description
The onset of covid-19 infection
Timepoint
Before study and after 3 and 6 months
Method of measurement
Clinical symptoms, Corona PCR, CT scan of the lungs

Secondary outcomes

1

Description
The severity of COVID-19
Timepoint
Before study and after 3 and 6 months
Method of measurement
Clinical feature, CT scan

Intervention groups

1

Description
Case group: The Isfahan educational hospital staff who are at risk of coronavirus receiving 200 mg of hydroxychloroquine tablets (Amin Pharmaceutical Company) orally twice a week for 3 months
Category
Prevention

2

Description
Control group: The Isfahan educational hospital staff who are at risk of corona virus who did not receive hydroxychloroquine tablet
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Omid hospital
Full name of responsible person
Elahe Nasri
Street address
Omid hospitl, Farshadi Ave, Isfahan Town
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818491754
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2

Recruitment center
Name of recruitment center
Isabn-e-Maryam hospital
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3

Recruitment center
Name of recruitment center
Khorshid Hospital
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4

Recruitment center
Name of recruitment center
Amin hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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Grant name
Isfahan Medical Sciences
Grant code / Reference number
199004
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Elahe Nasri
Position
Assisstant professor
Latest degree
Subspecialist
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Infectious diseases
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
File
When the data will become available and for how long
6 months later
To whom data/document is available
executor of plan
Under which criteria data/document could be used
Effectiveness of treatment
From where data/document is obtainable
executor of plan
What processes are involved for a request to access data/document
Coordinating with the project manager and the hospital director
Comments