

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

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

Protocol summary

Study aim

The comparison 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, Isabnmaryam, Khorshid, and Amin hospitals in Isfahan city who are an encounter with COVID-19 patients divided into the case (weekly use of Hydroxychlorokin 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 Chancellor, Isfahan University of Medical Sciences, Hezarjerib street, Isfahan

City

Isfahan

Province

Isfahan

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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2

Recruitment center

Name of recruitment center

Isabn-e-Maryam hospital

Full name of responsible person

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3

Recruitment center

Name of recruitment center

Khorshid Hospital

Full name of responsible person

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Ostandari Ave, Khorshid Hospital

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4

Recruitment center

Name of recruitment center

Amin hospital

Full name of responsible person

Elahe Nasri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Elahe Nasri

Street address

Omid Hospital, Motahari street, Isfahan, Iran

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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

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Position

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Person responsible for updating data

Contact

Name of organization / entity

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Latest degree

Subspecialist

Other areas of specialty/work

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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