

# 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, Isabnemaryam, 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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**Fax****Email**

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## 2

### Recruitment center

**Name of recruitment center**

Isabn-e-Maryam hospital

**Full name of responsible person**

Elahe Nasri

**Street address**

Shams Abad Ave, Isfahan Town, Isabn-e-Mryam Hospital

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## 3

### Recruitment center

**Name of recruitment center**

Khorshid Hospital

**Full name of responsible person**

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**Street address**

Ostandari Ave, Khorshid Hospital

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**Postal code**

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## 4

### Recruitment center

**Name of recruitment center**

Amin hospital

**Full name of responsible person**

Elahe Nasri

**Street address**

Amin hospital, Ebnesina St., Isfahan

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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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**Email**

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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**

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**Full name of responsible person**

elahe Nasri

**Position**

Assistant Professor

**Latest degree**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

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**Position**

Assistant Professor

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Subspecialist

**Other areas of specialty/work**

Infectious diseases

**Street address**

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**Postal code**

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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**