# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Nov 2026

## The prophylactic effect of Hydroxychloroquine on Novel Corona virus (COVID-19) in health care providers

### Protocol summary

**Study aim**
Determination of the prophylactic effect of hydroxychloroquine on the prevention of covid19 in medical staff in Arak

**Design**
A randomized clinical trial, controlled by 90 people (two equal groups (45 people)) from the health care staff (in Arak city) who are dealing with patients. One group will be given hydroxychloroquine and the other group will be given routine care.

**Settings and conduct**
At the beginning of the study, the conditions will be fully explained to the individuals, the conditions of the drugs will be explained, and people will also be told that they are randomly assigned to one of the two groups and will be reassured. Their information will remain confidential to the researcher and they can be removed from the study at any stage of the study.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria : 1. Have a consent to participate in the study 2. People working in medical centers in Arak 3. Lack of sensitivity to hydroxychloroquine 4. Lack of G6PD disease 5. Lack of porphyria 6. Lack of breastfeeding 7. Not getting pregnant 8. Lack of diabetes, kidney and liver disease, and skin problems Exclusion Criteria: 1- Lack of desire to continue the study 2- Having major side effects

**Intervention groups**
Hydroxychloroquine is a drug that was originally used to prevent and treat malaria. These drugs are known as anti-malarial drugs, and since the ocular side effects of hydroxychloroquine are less than those of chloroquine, most hydroxychloroquine is now prescribed to treat rheumatological diseases. In this study, participants in the intervention group would receive 400 mg of hydroxychloroquine for eight weeks, and those in the control group would receive routine care for diseases. It should be noted that both groups will receive routine care.

**Main outcome variables**
The incidence of the disease and its severity will be compared between the two groups

### General information

**Reason for update**
Protocol Change

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20151222025660N2**
Registration date: **2020-05-04, 1399/02/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-20, 1399/05/30**
Update count: **1**

**Registration date**
2020-05-04, 1399/02/15

**Registrant information**

**Name**
Ramin Parvizrad

**Name of organization / entity**
Arak University of Medical Sciences

**Country**
Iran (Islamic Republic of)

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+98 863222003

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-04-13, 1399/01/25

**Expected recruitment end date**
2020-07-15, 1399/04/25

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The prophylactic effect of Hydroxychloroquine on Novel Corona virus (COVID-19) in health care providers

**Public title**

The prophylactic effect of Hydroxychloroquine on Novel Corona virus

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

consent to participate in the study People working in medical centers in Arak city Lack of sensitivity to hydroxychloroquine Lack of G6PD Lack of porphyria No breastfeeding No pregnancy Lack of diabetes, kidney , liver and skin disease

**Exclusion criteria:**

Lack of desire to continue studying Having major side effects from medication

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

This study will conducted in two referral hospitals for COVID-19 in Arak. For logistical reasons, we will to randomly allocate the staff of one hospital in the intervention group and the other hospital in the control group.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Other

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

**Street address**

A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province, Iran

**City**

arak

**Province**

Markazi

**Postal code**

6258794163

**Approval date**

2020-03-15, 1398/12/25

**Ethics committee reference number**

IR.ARAKMU.REC.1398.345

## Health conditions studied

### 1

**Description of health condition studied**

COVID-19

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19, virus identified

## Primary outcomes

### 1

**Description**

The number of confirmed cases

**Timepoint**

At the beginning and 2 months after the start of the study

**Method of measurement**

Checklist

### 2

**Description**

Serum CRP levels and cellular immunity (cd8 / cd4 ratio) are assessed at the beginning and end of the study for all subjects.

**Timepoint**

At the beginning and 2 months after the start of the study

**Method of measurement**

Checklist

### 3

**Description**

the two groups will also be examined in terms of disease severity (need for intubation, ICU hospitalization) and absolute lymphocyte count.

**Timepoint**

At the beginning and 2 months after the start of the study

**Method of measurement**

Checklist

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: They will receive 400 mg of hydroxychloroquine (Tehran Darou, Iran) a week for eight weeks and also this group will receive routine care for Corona's new disease.
**Category**
Prevention

### 2

**Description**
Control group: They will receive routine care for Corona's new disease
**Category**
Other

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Valiasr Hospital
**Full name of responsible person**
Dr. Ramin Parvizrad
**Street address**
Khorram Ave, valiasr hospital
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### 2

**Recruitment center**
**Name of recruitment center**
Khansari Hospital
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Arak University of Medical Sciences
**Full name of responsible person**
Dr Alirza Kamali
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Khorram Ave., Valiasr Hospita
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**Phone**
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alikamaliir@yahoo.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Arak 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**
Arak University of Medical Sciences
**Full name of responsible person**
Dr.Ramin Parvizrad
**Position**
Assistant Professor
**Latest degree**
Specialist
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## Person responsible for scientific inquiries

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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**
All data is shared
**When the data will become available and for how long**
After completing the study
**To whom data/document is available**
Public
**Under which criteria data/document could be used**
There are no other conditions
**From where data/document is obtainable**
Phone number: 09127760893
**What processes are involved for a request to access data/document**
1 month after coordination with the executor whose number was mentioned above
**Comments**