

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 863222003

Email address

r.parvizrad@arakmu.ac.ir

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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2367816985

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2

Recruitment center

Name of recruitment center

Khansari Hospital

Full name of responsible person

Dr. Ramin Parvizrad

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8962456325

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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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8695325412

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alikalaliir@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

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Person responsible for updating data

Contact

Name of organization / entity
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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