Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 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
City
Arak
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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Alirza Kamali
Street address
Khorram Ave., Valiasr Hospita
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8695325412
Phone
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Email
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
Other areas of specialty/work
Emergency Medicine
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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