Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

evaluation of the effects of the 2-drug diet (hydroxychloroquine + umifenovir(Arbidol)) compared with Hydroxy chlorquine on the of mortality rate in patients with moderate symptoms of COVID-19 infections: A randomized interventional study in Imam Reza Hospital, Mashhad.

Protocol summary

Study aim
Evaluation of the effects of the 2-drug diet (Hydroxy chloroquine + umifenovir (Arbidol)) compared with Hydroxy chlorquine on the of mortality rate in patients with moderate symptoms of COVID-19 infections

Design
Clinical trial with a control and parallel group design of 100 patients, blinded, and randomized

Settings and conduct
This clinical trial is conducted on patients definitively diagnosed with COVID-19 with moderate symptoms. Patients with the inclusion criteria will be randomly assigned to the intervention and control group. The intervention group will receive a two-drug diet of Hydroxy chloroquine and Arbidol. Patients of the control group are selected from those who are routinely receiving Hydroxy chloroquine in Imam Reza Hospital and are similar to patients in the intervention group in terms of sex, age, sickness severity etc. The results of these two groups will be compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age range within 18 to 65; definitive diagnosis with COVID-19 with moderate symptoms; SpO2<93%; pulmonary infiltration. Non-inclusion criteria: pregnancy; having morbidities such as heart diseases; history of retinopathy; patient with severe conditions who will not last more than 48 hours; infection with HIV

Intervention groups
Intervention group: In this group, patients with moderate symptoms of COVID-19 take the two-drug diet of 200 mg Hydroxy chlorquine with 2 tablets every 12 hours in the first day and 1 every 12 hours up to 7 days in addition to 100 mg Arbidol every 8 hours 2 tablets for at least 7 days. Control group: patients in this group routinely receive 200 mg Hydroxy chlorquine with 2 tablets every 12 hours in the first day and 1 every 12 hours up to 7 days.

Main outcome variables
Fever; respiration rate; pulse rate, SpO2, WBC, number of lymphocytes; LDH; C reactive protein (CRP), findings of CT scan

General information

Reason for update
Considering the increase in the volume of the drug received from the ministry of health and also increase in the number of patients infected by COVID-19, the university vice dean for research decided to increase the sample size and at this moment, the randomized study is, with the permission of ethics committee, being conducted.

Acronym

IRCT registration information
IRCT registration number: **IRCT20200325046859N2**
Registration date: **2020-04-26, 1399/02/07**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-12, 1399/03/23**
Update count: **1**

Registration date
2020-04-26, 1399/02/07

Registrant information

Name
Rozita khodashahi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone

+98 51 3858 3845

Email address

khodashahir@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-22, 1399/02/03

Expected recruitment end date

2020-06-23, 1399/04/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

evaluation of the effects of the 2-drug diet (hydroxychloroquine + umifenovir(Arbidol)) compared with Hydroxy chlorquine on the of mortality rate in patients with moderate symptoms of COVID-19 infections: A randomized interventional study in Imam Reza Hospital, Mashhad.

Public title

effects of the 2-drug diet (hydroxychloroquine + umifenovir(Arbidol)) compared with Hydroxy chlorquine on the of mortality rate in patients with moderate symptoms of COVID-19 infections

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent for inclusion in the study Age range within 18 to 65 Intial symptoms during the first 12 days Diagnosis with COVID-19 is definitive Moderate symptoms of COVID-19 and need for hospitalization, SPO2<93%, pulmonary infiltration in chest radiography or CT scan and clinical judgment of a specialist

Exclusion criteria:

Pregnancy Having morbidities such as heart diseases which do not allow the use of treatment drugs History of retinopathy which does not allow the use of Hydroxy chlorquine. Patient with severe condition who will not last more than 48 hours Infection with HIV

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization will be carried out using table of random numbers available at 'www.randomization.com' website where the produced numbers are placed in sealed envelopes assigning each patient to one of the two groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The data analyst is unaware of the groups each patient belongs to.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2020-06-06, 1399/03/17

Ethics committee reference number

IR.MUMS.REC.1399.288

Health conditions studied

1

Description of health condition studied

COVID-19 disease

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified site

Primary outcomes

1

Description

Fever

Timepoint

Before and after treatment

Method of measurement

Thermometer

2

Description
Respiration rate
Timepoint
Before and after treatment
Method of measurement
Counting the number of breaths patients take per minute

3

Description
Findings of chest CT scan
Timepoint
Before and after treatment
Method of measurement
CT scan machine

4

Description
Pulse
Timepoint
Before, during and after treatment
Method of measurement
Patient monitoring device

5

Description
SpO2
Timepoint
Before and after treatment
Method of measurement
Patient monitoring device

6

Description
WBC
Timepoint
Before and after treatment
Method of measurement
Biochemical test

7

Description
Number of lymphocytes
Timepoint
Before and after treatment
Method of measurement
Biochemical test

8

Description
Lactate dehydrogenase
Timepoint
Before and after treatment
Method of measurement
Biochemical test

9

Description
C reactive protein (CRP)
Timepoint
Before and after treatment
Method of measurement
Biochemical test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, patients with moderate symptoms of COVID-19 take the two-drug diet of 200 mg Hydroxy chlorquine (Made by Amin Pharmaceutical Company) with 2 tablets every 12 hours in the first day and 1 every 12 hours up to 7 days in addition to 100 mg Arbidol (Made in Russia (received from the Ministry)) every 8 hours 2 tablets for at least 7 days.
Category
Treatment - Drugs

2

Description
Control group: patients in this group routinely receive 200 mg Hydroxy chlorquine (Made by Amin Pharmaceutical Company) with 2 tablets every 12 hours in the first day and 1 every 12 hours up to 7 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Rozita Khodashahi
Street address
Imam Reza Hospital, next to Imam Reza square, Ibne Sina street
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9137913316
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Email
khodashahir@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
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Postal code
91778-99191
Phone
+98 51 3841 2081
Email
ramresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Rozita Khodashahi
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Infectious diseases
Street address
Imam Reza Hospital, next to Imam Reza square, Ibne Sina street
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Person responsible for scientific inquiries

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Latest degree
Subspecialist
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Person responsible for updating data

Contact
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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 can be shared after patients are made unidentifiable.
When the data will become available and for how long
Data can be accessible 6 months after results are published.
To whom data/document is available
Data will be available for researchers in universities and other scientific institutes.
Under which criteria data/document could be used
Carrying out analysis on data is permitted.
From where data/document is obtainable
Data can be accessible through an email to the corresponding author.
What processes are involved for a request to access data/document
After sending a request email to the corresponding author, data will be sent in 1 month.
Comments