Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Hydroxychloroquine on Novel Coronavirus Disease (COVID-19) prevention in cancer patients under treatment

Protocol summary

Study aim
Determining the effect of hydroxychloroquine on the prevention of Novel Coronavirus Disease (COVID-19) in patients with cancer.

Design
This is a two-arm, parallel-group, triple-blind, randomised controlled trial.

Settings and conduct
During two months of treatment, the two groups were treated with hydroxychloroquine every other day with a 200 mg tablet or placebo, during this time they will be monitored for COVID-19 symptoms. If signs or symptoms occur (fever, cough, shortness of breath), they will be examined with a high resolution computerize tomography (CT) scan of the lungs and a nucleic acid amplification test (NAT) for the SARS-CoV-2 virus. Both the patient and the treating physician are blind to medication / placebo. The data analyser is also blinded regarding the allocated groups. This study is performed in five academic hospitals affiliated to Mashhad University of Medical Sciences.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients older than 15 years. Patients with curable Acute Lymphoblastic Leukemia. Patients with curable Acute Myeloblastic Leukemia. Patients with curable high-grade non-Hodgkin Lymphoma. Adult patients (over 15 years) with curable Breast cancer. Adult patients (over 15 years) with curable Colon cancer. Exclusion criteria: Known sensitivity to Hydroxychloroquine. Weight bellow 35 kilograms. History of retinopathy. History of any cardiac disease. Acute respiratory tract infection in the last 2 month. Having COVID-19 in the first two weeks of entering the trial. Having Diabetes Mellitus. Having immuno-suppressive disease other than cancer. Having chronic pulmonary disease. Taking immuno-suppressant drug other than chemotherapeutic agents for current cancer.

Intervention groups
Patients are randomly assigned to two groups, one being given hydroxychloroquine and the other is given placebo.

Main outcome variables
COVID-19 incidence rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200405046958N1**
Registration date: **2020-04-14, 1399/01/26**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-14, 1399/01/26**
Update count: **0**

Registration date
2020-04-14, 1399/01/26

Registrant information

Name
Mohammad Moeini Nodeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3801 2742

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moeininm@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

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

Expected recruitment end date
2020-06-14, 1399/03/25

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Hydroxychloroquine on Novel Coronavirus Disease (COVID-19) prevention in cancer patients under treatment

Public title

Prevention of Novel Coronavirus Disease by Hydroxychloroquine in cancer patients.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with curable Acute Lymphoblastic Leukemia Patients with curable Acute Myeloblastic Leukemia Patients with curable high-grade non-Hodgkin Lymphoma Patients with curable Breast cancer Patients with curable Colon cancer Age higher than 15 years

Exclusion criteria:

Known sensitivity to Hydroxychloroquine Weight lower than 35 kilograms History of retinopathy History of any cardiac disease Acute respiratory tract infection in the last 2 month Having novel Coronavirus in the first two weeks of entering the trial Diabetes Mellitus Immuno-suppressive disease other than cancer Chronic pulmonary disease Taking immuno-suppressive drugs other than cancer chemotherapy

Age

From **15 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed using randomly permuted blocks. By using online website (www.randomization.com) the randomization sequence will be produced by quadruple blocks.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patient and the physician do not know whether the patient is in the intervention or the control group. The data analyser will also be blinded regarding the intervention and control groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

MUMS (Mashhad University of Medical Sciences) medical ethics committee

Street address

Central Building of MUMS, Daneshgah Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2020-04-12, 1399/01/24

Ethics committee reference number

IR.MUMS.REC.1399.078

Health conditions studied

1

Description of health condition studied

COVID-19 disease

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

2

Description of health condition studied

Acute myeloid leukemia

ICD-10 code

C92.0

ICD-10 code description

Acute myeloblastic leukemia

3

Description of health condition studied

Acute lymphoblastic leukemia

ICD-10 code

C91.0

ICD-10 code description

Acute lymphoblastic leukemia [ALL]

4

Description of health condition studied

Breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

5

Description of health condition studied
Colon cancer
ICD-10 code
C18
ICD-10 code description
Malignant neoplasm of colon

6

Description of health condition studied
Diffuse large B cell lymphoma
ICD-10 code
C83.3
ICD-10 code description
Diffuse large B-cell lymphoma

Primary outcomes

1

Description
COVID-19 incidence rate in cancer patients under treatment.
Timepoint
Patients are examined and investigated if they become symptomatic during the 2 months of study.
Method of measurement
First, a history and physical examination are performed for the symptoms of COVID-19, and if the test is positive, a computerized tomography scan of the lungs and a nucleic acid amplification test for the SARS-CoV-2 virus.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention arm: Patients in this group receive 200 mg of hydroxychloroquine tablets (manufactured by Amin Pharmaceutical Company, Isfahan) every other day for 2 months. At the same time, specific cancer treatments are given.
Category
Prevention

2

Description
Control arm: Patients receive the placebo, which is similar to Amin's hydroxychloroquine tablets, one every other day. Cancer treatment of these patients is done according to the standard during this period.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
Mohammad Moeini Nodeh
Street address
Ghaem hospital, Ahmadabad Ave, Shariati Sq.
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Mashhad
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Postal code
9175856499
Phone
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moeininm@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Central building of Mashhad University of Medical Sciences, Daneshgah Ave.
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+98 51 3841 3006
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tafaghodim@mums.ac.ir
Web page address
https://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

Mohammad Moeini Nodeh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Hematology Oncology

Street address

Internal medicine department, Ghaem hospital, Ahmadabad Ave, Shariati Sq.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable