

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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 computerized 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 analyst 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 below 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)

Phone

+98 51 3801 2742

Email address

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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9175856499

Phone

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Email

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

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Central building of Mashhad University of Medical Sciences, Daneshgah Ave.

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Email

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

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Full name of responsible person

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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