

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Clinical trial of the effect of crocetin in improving the clinical and laboratory symptoms of patients with COVID-19

Protocol summary

Study aim

Evaluation the effect of crocetin in improving the clinical and laboratory symptoms of patients with COVID-19

Design

A randomized, blinded, placebo-controlled clinical trial with a parallel-group design of 40 patients, randomizing with the table of random numbers.

Settings and conduct

This study will be performed on outpatients. In this study, 40 patients with COVID-19 disease were selected and randomly assigned to two groups of 20 individuals. Patients in the standard diet control group will receive standard coronavirus treatment with a placebo. In addition to the standard diet, patients in the treatment group will be treated with 7.5 mg of crocetin three times a day for at least 2 weeks. Patients are monitored at intervals of 3 days, 1 week and 2 weeks after receiving the drug or placebo in terms of time interval until clinical and laboratory symptoms improve.

Participants/Inclusion and exclusion criteria

People over 18 years of age with a diagnosis of coronavirus based on clinical and laboratory symptoms; home quarantine and outpatients

Intervention groups

The control group receives standard anti-coronavirus drugs with placebo. In addition to the common anti coronavirus drugs, the treatment group also receives crocetin capsules.

Main outcome variables

Time interval until lymphopenia improves Time interval until CRP normalizes Time interval until clinical symptoms improve (fever, cough, and myalgia)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20081019001369N3**

Registration date: **2020-04-11, 1399/01/23**

Registration timing: **prospective**

Last update: **2020-04-11, 1399/01/23**

Update count: **0**

Registration date

2020-04-11, 1399/01/23

Registrant information

Name

Hossein Hosseinzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3180 1193

Email address

hosseinzadehh@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of crocetin in improving the clinical and laboratory symptoms of patients with COVID-19

Public title

Effect of crocetin on COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with COVID-19 symptoms Indication of home quarantine and outpatient medication

Exclusion criteria:

Patients over 65 years of age Patients connected to a catheter or under chemotherapy Patients taking cytotoxic drugs or corticosteroids Child patients Pregnant and lactating patients Diabetic patients Patients with severe renal insufficiency as well as liver failure

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization in three stages: 1- Random sequence generation: this step simple or limited randomization will be done based on a table of random numbers 2- Allocation concealment: which is done in the form of coded boxes (numbered drug containers) with a random sequence. In this method, a number of boxes with the same shape and size are numbered based on random sequences and contain drugs or placebo that have a completely similar appearance. 3- Execution of random allocation process: A: Identify the person who creates the random sequence B: A person who evaluates and registers researchers in terms of inclusion and exclusion criteria C: The person who assigned the participants to the groups: infectious diseases specialist The main researcher of the project, who creates a random sequence, does not interfere in other stages of randomization, including registration and allocation of participants, and the person involved in creating a random program is separate from other researchers.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug and placebo are given as a same-color and -size capsules in boxes labeled with the letters A and B in box. The medical staff, the patient and the data collector are not aware of the nature of the drug or placebo and only the executor of the research project is aware of the nature of the contents of the two capsules.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Research Ethics Committee

Street address

Qods Town (West), between Flamak South and Zarafshan, Simai Iran St. - Central Headquarters of the Ministry of Health, Treatment and Medical Education, Block A, 13th Floor

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۹۴۳۴۷۱

Approval date

2020-04-06, 1399/01/18

Ethics committee reference number

IR.MUMS.REC.1399.052

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19 disease

Primary outcomes

1

Description

Time interval until clinical symptoms improve

Timepoint

3 days, 1 week and 2 weeks after treatment

Method of measurement

time of recovery

Secondary outcomes

1

Description

Fever

Timepoint

3 days, 1 week and 2 weeks after treatment

Method of measurement

Thermometer

DehghanMJ@mums.ac.ir

2

Description

Lymphopenia

Timepoint

3 days, 1 week and 2 weeks after treatment

Method of measurement

Cell counter device

3

Description

CRP

Timepoint

3 days, 1 week and 2 weeks after treatment

Method of measurement

CRP kit

Intervention groups

1

Description

Intervention group: In addition to the standard treatment regimen for COVID-19, the crocetin capsule 22.5 mg (7.5 mg, three times a day) will be given for 2 weeks.

Category

Treatment - Drugs

2

Description

Control group: Patients on the standard treatment regimen for COVID-19 will receive placebo capsules 3 times a day for 2 weeks. The placebo is formulated in capsules of the same shape and size as the drug capsules and contains inert ingredients.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hasheminejad Hospital

Full name of responsible person

Javad Dehghan Nayyeri

Street address

Mofateh boulevard, Vahid street

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3273 7011

Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghdi

Street address

Daneshgah St.

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9138813944

Phone

+98 51 3841 1538

Email

TafaghodiM@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

Hossein Hosseinzadeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Blv. Vakilabad2-School of Pharmacy, 1365-91775

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

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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

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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