Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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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

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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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
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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
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