Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Clinical trial of berberine against COVID-19

Protocol summary

Study aim
Evaluation the effect of berberine in covid-19 patients
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 placebo. In addition to the standard diet, patients in the treatment group will be treated with 300 mg of berberine 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-corona virus drugs, the treatment group also receives berberine.
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: **IRCT20081019001369N2**
Registration date: **2020-04-07, 1399/01/19**
Registration timing: **prospective**
Last update: **2020-04-07, 1399/01/19**
Update count: **0**
Registration date
2020-04-07, 1399/01/19

Registrant information
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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 berberine against COVID-19

Public title
Effect of berberine 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 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

Medical Ethics Committee of Mashhad University of Medical Sciences

Street address

Blv.Vakilabad 2- School of Pharmacy-1365-91775

City

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Province

Razavi Khorasan

Postal code

9177948954

Approval date

2020-03-31, 1399/01/12

Ethics committee reference number

IR.MUMS.REC.1399.030

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
In addition to the standard treatment regimen for COVID-19, the berberine hydrochloride capsule (Pharmaceutical grade) 300 mg will be given three times a day for 2 weeks. Berberine capsule (300 mg) is formulated at the School of Pharmacy with the inert ingredients of aerosol and avicel.
Category
Treatment - Drugs

2

Description
Control group: Patients on the standard treatment regimen for COVID-19 will receive placebo capsules three times a day for 2 weeks. The placebo is formulated in capsules of the same shape and size as the drug capsules and contains avicel and aerosil.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Javad Dehghan Nayyeri
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Sponsors / Funding sources

1

Sponsor
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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
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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
Not applicable