

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 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

###### 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 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**

Mashhad

**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

##### Street address

Imam Reza Square

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9137913316

##### Phone

+98 51 3854 3031

##### Email

DehghanMJ@mums.ac.ir

## 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.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

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

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948954

##### Phone

+98 51 3180 1193

##### Fax

+98 51 1882 3251

**Email**

hosseinzadehh@mums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hossein Hosseinzadeh

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Mashhad University of Medical Sciences

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Professor

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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