

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jul 2026

### Effect of curcumin-piperine supplementation on disease duration, severity and clinical signs, and inflammatory factors in patients with coronavirus (COVID-19): A randomized, double-blind, placebo-controlled clinical trial study

#### Protocol summary

##### Study aim

Determination of the effect of curcumin-piperine supplementation on disease duration, severity, and clinical signs and inflammatory factors in patients with coronavirus (COVID-19): A randomized, double-blind, placebo-controlled clinical trial study

##### Design

This is a randomized, placebo-controlled, double-blind parallel-group clinical trial. One hundred participants will be randomly allocated to receive curcumin-piperine supplement per day (25 inpatients and 25 outpatients) or placebo (25 inpatients and 25 outpatients).

##### Settings and conduct

In this study, patients with coronavirus will be recruited from hospitals of Isfahan University of Medical Sciences. Subjects will be stratified according to gender. Random assignment will be done by the use of a table of random numbers. The enrolling participants, and assigning participants to the groups will be carried out by a relevant specialist. The curcumin-piperine supplement and its placebos will be packed in similar boxes, and the researcher and the patients will not be aware of the content of the pack until the end of the study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Tendency to participate in the study; People aged 18-65 years; Diagnosis of Covid-19 based on the PCR test. Exclusion criteria: Age less than 20 and more than 75 years; Taking warfarin; Sensitivity to herbal products such as turmeric and pepper

##### Intervention groups

Individuals will be randomly assigned to two groups to receive the curcumin-piperine supplement (1000 mg/day of curcumin and 10 mg/day of piperine) or placebo (1010 mg of maltodextrin) for 2 weeks.

##### Main outcome variables

CT of the chest, body temperature, length of hospital

stay, hs-CRP, ESR, ALT, AST, LDH, BUN, creatinine, CBC, blood oxidative stress indices (SOD, MDA, TAC), Albumin, Severity of the disease, severity and number of coughs

#### General information

##### Reason for update

Correction of typos and updating of the sampling period

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20121216011763N46**

Registration date: **2020-05-04, 1399/02/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-10-31, 1399/08/10**

Update count: **1**

##### Registration date

2020-05-04, 1399/02/15

##### Registrant information

###### Name

Gholamreza Askari

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1792 2110

###### Email address

askari@mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-04, 1399/02/15  
**Expected recruitment end date**  
 2021-04-19, 1400/01/30  
**Actual recruitment start date**  
 empty  
**Actual recruitment end date**  
 empty  
**Trial completion date**  
 empty

**Scientific title**  
 Effect of curcumin-piperine supplementation on disease duration, severity and clinical signs, and inflammatory factors in patients with coronavirus (COVID-19): A randomized, double-blind, placebo-controlled clinical trial study

**Public title**  
 Effect of curcumin-piperine in patients with coronavirus (COVID-19)

**Purpose**  
 Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Tendency to participate in the study People aged 18-65 years Diagnosis of Covid-19 based on the PCR test  
**Exclusion criteria:**  
 Age less than 20 and more than 75 years Taking warfarin Sensitivity to herbal products such as turmeric and pepper

**Age**  
 From **20 years** old to **75 years** old

**Gender**  
 Both

**Phase**  
 N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
 Target sample size: **100**

**Randomization (investigator's opinion)**  
 Randomized

**Randomization description**  
 Randomly, based on the permuted block randomization method, using blocks of 4 that will be blocked based on gender variables and will be assigned to one of two curcumin-piperine and placebo groups. The enrolling participants, and assigning participants to the groups will be carried out by a trained nutritionist. Researchers will not be informed about the randomization process until the completion of data analyses.

**Blinding (investigator's opinion)**  
 Double blinded

**Blinding description**  
 This study is a double-blind clinical trial (participant, researcher). The curcumin-piperine supplement and its placebo will be packaged in similar boxes, and the

researcher and patients will not be informed of the contents of the packs until the end of the study.

**Placebo**  
 Used  
**Assignment**  
 Parallel  
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

##### Street address

Hezarjarib Ave., Isfahan University of Medical Sciences

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2020-04-18, 1399/01/30

#### Ethics committee reference number

IR.MUI.MED.REC.1399.049

## Health conditions studied

### 1

#### Description of health condition studied

coronavirus (covid-19) disease

#### ICD-10 code

U07.02

#### ICD-10 code description

COVID-19 Disease

## Primary outcomes

### 1

#### Description

CT of the chest

#### Timepoint

Before intervention and 2 weeks after intervention

#### Method of measurement

Find out - Photos - CT

### 2

#### Description

Body temperature

#### Timepoint

Before intervention and 2 weeks after intervention

**Method of measurement**

By using clinical thermometer

**3****Description**

Duration of hospitalization

**Timepoint**

At the time of discharge from the hospital

**Method of measurement**

By Using the patient's medical record

**4****Description**

hs-CRP

**Timepoint**

Before intervention and 2 weeks after intervention

**Method of measurement**

Enzymatic method

**5****Description**

ESR

**Timepoint**

Before intervention and 2 weeks after intervention

**Method of measurement**

Enzymatic method

**6****Description**

ALT

**Timepoint**

Before intervention and 2 weeks after intervention

**Method of measurement**

Enzymatic photometric method

**7****Description**

AST

**Timepoint**

Before intervention and 2 weeks after intervention

**Method of measurement**

Enzymatic photometric method

**8****Description**

LDH

**Timepoint**

Before intervention and 2 weeks after intervention

**Method of measurement**

Enzymatic photometric method

**9****Description**

BUN

**Timepoint**

Before intervention and 2 weeks after intervention

**Method of measurement**

urine sample

**10****Description**

creatinine

**Timepoint**

Before intervention and 2 weeks after intervention

**Method of measurement**

by laboratory kit

**11****Description**

CBC

**Timepoint**

Before intervention and 2 weeks after intervention

**Method of measurement**

blood sample

**12****Description**

blood oxidative stress indices ( SOD, MDA, TAC)

**Timepoint**

Before intervention and 2 weeks after intervention

**Method of measurement**

By using available commercial kits

**13****Description**

Albumin

**Timepoint**

Before intervention and 2 weeks after intervention

**Method of measurement**

blood sample

**14****Description**

Severity of the disease

**Timepoint**

Before intervention and 2 weeks after intervention

**Method of measurement**

By using clinical and laboratory evaluations

**15****Description**

severity and number of coughs

**Timepoint**

Before intervention and 2 weeks after intervention

**Method of measurement**

Visual analogue scales (VAS) for cough

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention group: Two curcumin-piperine capsules (500 mg of curcumin + 5 mg of piperine) will be given daily for 2 weeks after lunch and dinner.

### Category

Treatment - Other

## 2

### Description

Control group: 2 placebo capsules ( containing 505 mg of maltodextrin) will be given daily after lunch and dinner for 2 weeks.

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Hospitals affiliated with Isfahan University of Medical Sciences

#### Full name of responsible person

Gholamreza Askari

#### Street address

Ostandari Ave.

#### City

Isfahan

#### Province

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#### Postal code

8174673461

#### Phone

+98 31 1792 2110

#### Email

askari@mui.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Shaghayegh Haghjou

#### Street address

Hezar Jarib Ave, Isfahan University of Medical Sciences

#### City

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#### Province

Isfahan

#### Postal code

81746-73461

#### Phone

+98 31 3668 8138

#### Email

sh\_haghjoo@med.mui.ac.ir

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

#### Full name of responsible person

Gholamreza Askari

#### Position

Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Nutrition

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Hezarjarib Ave

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#### Postal code

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#### Phone

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#### Email

askari@mui.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Gholamreza Askari

#### Position

Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Gholamreza Askari  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Nutrition  
**Street address**  
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**Email**

askari@mui.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

No - There is not a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

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

### Title and more details about the data/document

The collected deidentified for the primary outcome measure only will be shared.

### When the data will become available and for how long

12 months after publication

### To whom data/document is available

Available for people working in academic institutions

### Under which criteria data/document could be used

To conduct similar studies

### From where data/document is obtainable

askari@mui.ac.ir

### What processes are involved for a request to access data/document

The data will send as soon as possible, after receiving the request.

### Comments