Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 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

Isfehan

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
Isfehan
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
Isfahan
Province
Isfehan
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
Street address
Hezarjarib Ave
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 1378
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
Nutrition
Street address
Hezarjarib Ave

City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 1792 2110
Email
askari@mui.ac.ir

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
Isfahan University of Medical Sciences, Hezarjarib St., Isfahan
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 1792 2110
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