

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of the effect of curcumin-piperine supplementation in patients with coronavirus admitted to the intensive care unit (ICU): a double-blind clinical trial study

Protocol summary

Study aim

Evaluation of the effect of curcumin-piperine supplementation in patients with coronavirus admitted to the intensive care unit (ICU)

Design

This study is a clinical trial with a randomized, parallel double-blind control group, in which 50 patients with coronavirus will be divided into two groups receiving curcumin-piperine supplement (n = 30) and placebo (n = 30).

Settings and conduct

In this study, people with coronavirus in Al-Zahra Hospital will be included in the study. Random allocation will be done using a random number table. Entry of individuals and assignment of each person to one of the two groups will be done by the relevant specialist. Curcumin-piperine supplement and placebo will be packaged in similar boxes and the researcher and patients will not be informed of the contents of the packages until the end of the study.

Participants/Inclusion and exclusion criteria

Entry requirements: Willingness to participate in the study, Age 20-80 years, Diagnosis of Covid-19 based on PCR findings
No entry conditions: Sensitivity to plant products such as turmeric and pepper
Patients with a history of underlying disease
Taking anticoagulants,
People who are in severe stages of pregnancy and lactation, septic shock or sepsis.

Intervention groups

1) Patients who receive 3 capsules of 500 mg per day of curcumin-piperine for 7 days (30 people) (intervention)
Group 2) Patients receiving 3 placebo capsules for 14 days, each capsule containing 500 mg of maltodextrin per day (control) (30 patients)

Main outcome variables

Body temperature, ESR and CRP, length of hospital stay, extent and severity of patients' cough, (ALT, AST, LDH),

(BUN, Creatinine), (CBC), NUTRIC score, APACHE II and SOFA score, mean blood sugar, ALBUMIN

General information

Reason for update

Due to the changes made, the need to make corrections was as follows: 1. The age of the participants is from 20 to 80 years 2. The number of samples reached 60 people 3. The intervention period was reduced to 7 days.

Acronym

IRCT registration information

IRCT registration number: **IRCT20121216011763N52**

Registration date: **2021-05-13, 1400/02/23**

Registration timing: **prospective**

Last update: **2021-05-23, 1400/03/02**

Update count: **1**

Registration date

2021-05-13, 1400/02/23

Registrant information

Name

Gholamreza Askari

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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askari@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-15, 1400/02/25

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of curcumin-piperine supplementation in patients with coronavirus admitted to the intensive care unit (ICU): a double-blind clinical trial studyCommunity Verified icon

Public title

Evaluation of the effect of curcumin in coronary hospitalized patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to participate in the study Age 20-80years
Diagnosis of Covid-19 based on clinical findings and PCR findings
Gastrointestinal tract with normal function and intestinal nutrition criteria

Exclusion criteria:

Age less than 20 and more than 80 years
Sensitivity to plant products such as turmeric and pepper
Impossibility of intestinal feeding in the first 48 hours of admission
Patients who are hospitalized in the intensive care unit for less than 48 hours. Patients who are expected to die within 12 hours of admission to the intensive care unit. Patients who do not have an indication for intestinal nutrition on the first day and are confirmed and predicted based on the diagnosis of the intensive care unit that they will not be able to receive intestinal nutrition in the future. (Nausea, persistent vomiting, ileus, intestinal obstruction, uncontrolled diarrhea (> 500 ml per day), high-output fistula (> 500 ml per day), intestinal inaccessibility, incomplete resuscitation and hemodynamic instability
Patients with BMI <18.5kg / m2 admitted to the intensive care unit. Patients who receive nutritional support through complete intravenous feeding
Patients with a history of underlying disease such as congenital and immune disorders, renal and hepatic insufficiency and pancreatitis.Community Verified icon
Taking anticoagulants such as heparin, warfarin, aspirin, etc. Pregnancy and lactation
Severe septic shock or sepsis
Dissatisfaction of the patient or her legal guardian

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting the participants based on the inclusion criteria and obtaining the consent of the patients or their companions, the participants will be randomly divided into two groups, intervention and placebo and will be studied for 1 weeks (7 days). For this purpose, 60 patients admitted to the ICU who have already been diagnosed with COVID19 by PCR will be randomly divided into two groups (30 in the intervention group and 30 in the control group) using a random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to carry out this research in a double-blind manner, before starting the study, the total of the relevant capsules Both intervention and control groups, which are similar in shape, color, and appearance, are coded A and B by someone other than the researcher to ensure that the researcher does not know the type of capsules received by both groups. Participants who were randomly divided into groups A and B received the pills for a week without knowing that they were in the supplement or placebo group.

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

Isfahan University of Medical Sciences, Hezar Jerib Avenue

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Province

Isfahan

Postal code

8174673461

Approval date

2021-05-08, 1400/02/18

Ethics committee reference number

IR.MUI.RESEARCH.REC.1400.057

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

Body temperature

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

By using clinical thermometer

2

Description

hs-CRP

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

Enzymatic method

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

severity and number of coughs

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

Visual analogue scales (VAS) for cough

5

Description

ALT

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

Enzymatic photometric method

6

Description

AST

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

Enzymatic photometric method

7

Description

LDH

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

Enzymatic photometric method

8

Description

BUN

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

Biochemical test by enzymatic method by Hitachi 902 device

9

Description

creatinine

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

Biochemical test by enzymatic method by Hitachi 902 device

10

Description

CBC

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

Device analysis using cell counter device (hematology analyzer)

11

Description

Albumin

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

Biochemical test by enzymatic method by Hitachi 902 device

12

Description

Blood sugar

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

Biochemical test by enzymatic method by Hitachi 902 device

13

Description

ESR

Timepoint

Before intervention and 2 weeks after intervention
Method of measurement
Enzymatic method

14

Description
NUTRIC score
Timepoint
Before and after the intervention
Method of measurement
By scoring a questionnaire including APACHE II and SOFA

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients receiving 3 capsules of 500 mg per day of curcumin-piperine (manufactured by Sami Lab India) for 7 days (a total of 1500 mg of curcumin per day and 15 mg of piperine per day) (30 N). These supplements are given to patients at 9 am, 3 pm and 9 pm, 6 hours apart.
Category
Treatment - Drugs

2

Description
Control group: Patients who receive 3 placebo capsules for 7 days, each capsule containing 500 mg of maltodextrin per day (total 1500 mg of maltodextrin) (30 people) These supplements at 9 am, 3 pm and 9 pm, 6 hours apart It is given to patients.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Province
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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
دانشیار
Latest degree
Specialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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