Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 studyCommunity Verified icon

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)

Phone

+98 31 1792 2110

Email address

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 committe of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jerib Avenue
City
Isfahan
Province
Isfehan
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

En 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

Ghulam Reza Askari

Street address

Sofe Boulevard

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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

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Province

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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

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

Other areas of specialty/work

Nutrition

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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

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Latest degree
Specialist

Other areas of specialty/work
Nutrition

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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