

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of curcumin piperine supplementation on inflammation, length of stay, and 28-day mortality in patients with sepsis admitted to the intensive care unit (ICU): a double-blind randomized controlled clinical trial

Protocol summary

Study aim

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

Design

This study is a randomized double-blind clinical trial on 66 patients. Randomization is performed by Excel software

Settings and conduct

This double-blind study was performed on patients with sepsis in the ICU of Alzahra Hospital in Isfahan. The intervention group received curcumin supplement for 1 week and the control group received malto dextrin supplement for 1 week. In this study, blindness is performed on researchers and patients who participated in the project.

Participants/Inclusion and exclusion criteria

Participants: 66 patients aged 20 to 75 years with sepsis admitted to the intensive care unit (ICU) Inclusion criteria: age 20-75 years, gastrointestinal tract with normal function and diagnosis of sepsis Non-entry conditions: Impossibility of intestinal feeding in the first 48 hours of admission, Patients who are expected to die within 12 hours of admission to the intensive care unit. Patients with BMI <18.5 kg / m² admitted to the intensive care unit.

Intervention groups

Group 1) Patients who receive 2 placebo capsules for 7 days, each capsule containing 500 mg of maltodextrin per day (total 1000 mg of maltodextrin) (33 patients)
Group 2) Patients receiving two 500 mg capsules of curcumin-piperine per day for 7 days (total 1000 mg of curcumin per day and 10 mg of piperine per day) (33 patients)

Main outcome variables

Inflammation and infection in patients with sepsis in the ICU

General information

Reason for update

"To enhance the statistical power of the study, we propose increasing the sample size to 66 participants and revising the age-related (20-75 years) inclusion criteria."

Acronym

IRCT registration information

IRCT registration number: **IRCT20150613022681N4**

Registration date: **2021-01-02, 1399/10/13**

Registration timing: **prospective**

Last update: **2025-06-02, 1404/03/12**

Update count: **2**

Registration date

2021-01-02, 1399/10/13

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 911 195 1374

Email address

alikiaib@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-02-03, 1399/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of curcumin piperine supplementation on inflammation, length of stay, and 28-day mortality in patients with sepsis admitted to the intensive care unit (ICU): a double-blind randomized controlled clinical trial

Public title

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

Purpose

Basic science

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 20-75 years Gastrointestinal tract with normal function and intestinal nutrition criteria Diagnosis of sepsis is based on blood culture and the approval of an ICU, anesthesiologist and infectious disease specialist

Exclusion criteria:

Impossibility of intestinal feeding in the first 48 hours of admission Any history of underlying heart disease 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 Patients with BMI <18.5 kg / 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 uncontrolled diabetes, congenital and immune disorders, renal and hepatic insufficiency, and pancreatitis. 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 **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyst

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be conducted using the block randomization method (permuted blocked randomization). depending on the sample size, each block includes 4 characters and will be used AABB combination. In the following, all possible modes from the combination will be listed and a code will be allocated to each patient. This will be done using a random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

To blind both patients and investigators, in the beginning, cans containing curcumin supplement and placebo were coded as A and B by a person other than the researcher to ensure the researcher and participants were not informed about the types of supplement received by participants

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 street, Esfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-11-29, 1399/09/09

Ethics committee reference number

IR.MUI.MED.REC.1399.759

Health conditions studied**1****Description of health condition studied**

Sepsis

ICD-10 code

A41

ICD-10 code description

Other sepsis

Biochemical test by enzymatic method by Hitachi 902 device

Primary outcomes

1

Description

Inflammation (via hs-CRP, Albumin, pre Albumin indices)

Timepoint

Before and after the intervention

Method of measurement

Measurement of inflammatory markers by serum

2

Description

mortality 28 days

Timepoint

Before and after the intervention

Method of measurement

Use official statistics

3

Description

Duration of hospitalization

Timepoint

Before and after the intervention

Method of measurement

Use of questionnaire

Secondary outcomes

1

Description

Change in the number of red blood cells

Timepoint

Before and after the intervention

Method of measurement

Device analysis using cell counter device (hematology analyzer)

2

Description

Serum concentration of lipid profiles including triglyceride, cholesterol, HDL, LDL

Timepoint

Before and after the intervention

Method of measurement

Biochemical test by enzymatic method by Hitachi 902 device

3

Description

Fasting Blood Sugar Concentration

Timepoint

Before and after the intervention

Method of measurement

4

Description

Serum total protein

Timepoint

Before and after the intervention

Method of measurement

Biochemical test by enzymatic method by Hitachi 902 device

5

Description

BUN

Timepoint

Before and after the intervention

Method of measurement

Biochemical test by enzymatic method by Hitachi 902 device

6

Description

Blood prolactin

Timepoint

Before and after the intervention

Method of measurement

ELISA method

7

Description

serum albumin

Timepoint

Before and after the intervention

Method of measurement

Biochemical test by enzymatic method by Hitachi 902 device

8

Description

Serum creatinine

Timepoint

Before and after the intervention

Method of measurement

Biochemical test by enzymatic method by Hitachi 902 device

Intervention groups

1

Description

Intervention group: Patients receiving two 500 mg capsules of curcumin-piperine per day for 7 days (total 1000 mg of curcumin per day and 10 mg of piperine per day) (33 patients)

Category

Treatment - Drugs

2

Description

Control group: Intervention group: Patients receiving 2 placebo capsules for each day containing 500 mg of maltodextrin per day (total 1000 mg of maltodextrin) (33 patients) for 7 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital of Isfahan

Full name of responsible person

Babak Alikiaii

Street address

Al-Zahra Hospital of Isfahan, Softe Boulevard, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjoo Javanmard

Street address

Hezar Jarib

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

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

Babak Alikiaii

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Practitioner

Street address

Hezarjarib

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3620 1293

Email

alikiaii@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Babak Alikiaii

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Practitioner

Street address

Hezarjarib

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3620 1293

Email

alikiaii@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Babak Alikiaii

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Practitioner

Street address

Hezarjarib

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3620 1293

Email

alikiaii@med.mui.ac.ir

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

Not applicable

Title and more details about the data/document

All data can be shared at the request of individuals

When the data will become available and for how long

Six months after publishing the results.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

By sending an email to the following address that belongs to the executor of the project
alikiaii@med.mui.ac.ir

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

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments