Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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
alikiaiib@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 scienece
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 analyser

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
Isfehan
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

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
Biochemical test by enzymatic method by Hitachi 902 device

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, Soffe Boulevard, Isfahan
City
Isfahan
Province
Isfehan
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
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Hezar Jarib
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Province
Isfehan
Postal code
8174673461
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+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
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Person responsible for updating data

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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
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
alikiaiib@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