

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

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

Protocol summary

Study aim

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

Design

This double-blind, randomized trial is performed by Excel software on 50 patients.

Settings and conduct

In this double-blind randomized clinical trial study, 50 patients aged 18 to 70 years with multiple trauma admitted to the intensive care unit (ICU) of Al-Zahra Hospital are randomly divided into two groups after having inclusion criteria:

Participants/Inclusion and exclusion criteria

Participants: 50 patients aged 18 to 70 years with multiple trauma admitted to the intensive care unit (ICU)
Inclusion criteria: , gastrointestinal tract with normal function and intestinal nutrition criteria, diagnosis of sepsis based on blood culture and approval of an ICU and anesthesiologist and infectious disease specialist
Exclusion criteria: Impossibility of intestinal nutrition in the first 48 hours of admission, any history of underlying heart disease, and 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 with BMI <18.5kg / m2 were admitted to the intensive care unit. Patients who receive nutritional support with complete intravenous feeding.

Intervention groups

Group 1) Patients receiving two placebos, each capsule contained 250 mg capsules of maltodextrin (total of 500 mg daily) per day for 7 days (n = 25) Group 2) Patients receiving two 250 mg curcumin-phytosomal capsules (total of 500 mg daily) for 7 days (25 patients)

Main outcome variables

Inflammation, length of stay and mortality 28 days in patients with multiple trauma admitted to ICU

General information

Reason for update

Due to assigning the ICU of Al-Zahra Hospital to COVID-19 for a long time, some very minor changes were included in the implementation method.

Acronym

IRCT registration information

IRCT registration number: **IRCT20090306001747N1**

Registration date: **2021-01-12, 1399/10/23**

Registration timing: **prospective**

Last update: **2023-01-17, 1401/10/27**

Update count: **2**

Registration date

2021-01-12, 1399/10/23

Registrant information

Name

Saeed Abbasi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1625 5555

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-22, 1400/04/31
Expected recruitment end date
 2022-09-21, 1401/06/30
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

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

Public title
 Evaluation of the effect of phytosomal curcumin supplementation in multiple trauma

Purpose
 Basic science

Inclusion/Exclusion criteria
Inclusion criteria:
 Age 18-70 years Gastrointestinal tract with normal function and intestinal nutrition criteria Diagnosis of moderate or severe trauma based on GCS index (4-15) Trauma diagnosis based on Injury Severity Score (ISS) between minor to severe
Exclusion criteria:
 Impossibility of intestinal feeding in the first 48 hours of admission Any history of heart disease 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 and will not be able to receive intestinal nutrition in the future. (Nausea, persistent vomiting, ileus, intestinal obstruction, uncontrolled diarrhea (> 500 ml / day), high-output fistula (> 500 ml / 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 diabetes, congenital and immune disorders, renal and hepatic insufficiency, and pancreatitis. Taking anticoagulants such as heparin, warfarin, aspirin, etc. The unwillingness of the patient or his legal guardian to participate in the project Patients who are hospitalized in the intensive care unit for less than 48 hours Pregnancy and lactation Severe septic shock or sepsis

Age
 From **18 years** old to **70 years** old

Gender
 Both

Phase
 3

Groups that have been masked

- Participant
- Care provider
- Investigator

- Outcome assessor
- Data analyst

Sample size
 Target sample size: **50**

Randomization (investigator's opinion)
 Randomized

Randomization description
 For randomization, the randomized blocking method and spss software will be used, so that according to the sample size, the size of the blocks is 4 and AAB combinations will be used. In the following, all possible modes of the combination of 4 will be listed and for each one, a code will be considered and individuals will be assigned based on them. This will be done using a random number table.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 In order for this research to be double-blind, at the beginning of the study, a set of cans containing curcumin and placebo supplements that are similar in shape and appearance were coded as A and B by someone other than the researcher, then a person who has no information about supplements and placebo The group that does not know whether it is a supplement or a placebo is poured into cans A and the other group into cans B so that the researchers and participants do not know the type of supplement received by each 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
 hezarjarib
City
 isfahan
Province
 Isfahan
Postal code
 8174673461

Approval date
 2020-11-29, 1399/09/09

Ethics committee reference number
 IR.MUI.MED.REC.1399.758

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

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 existing 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 blood cells

Timepoint

Before and after the intervention

Method of measurement

Blood cell count test

2

Description

Blood sugar changes

Timepoint

Before and after the intervention

Method of measurement

Biochemical test by enzymatic method by Hitachi 902 device

3

Description

Serum total protein

Timepoint

Before and after the intervention

Method of measurement

Biochemical test by enzymatic method by Hitachi 902 device

4

Description

BUN

Timepoint

Before and after the intervention

Method of measurement

Biochemical test by enzymatic method by Hitachi 902 device

5

Description

liver enzymes

Timepoint

Before and after the intervention

Method of measurement

Biochemical test by enzymatic method by Hitachi 902 device

6

Description

Lactate Dehydrogenase (LDH)

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

9

Description

NUTRIC score

Timepoint

Before and after the intervention

Method of measurement

By scoring a questionnaire including APACHE II and SOFA

Intervention groups

1

Description

Intervention group: Patients receiving two 250 mg curcumin-phytosomal capsules (total of 500 mg daily) for 7 days (25 patients)

Category

Treatment - Drugs

2

Description

Control group: Patients receiving placebo for 7 days, two 250 mg maltodextrin capsules per day (25 patients)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Saeed Abbasi

Street address

Sefa Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Shaghayegh Haghjoo

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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

Mohammad Bagherniya

Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
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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

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after people have requested.

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
s_abbasi@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