Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Oct 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
s_abbasi@med.mui.ac.ir

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 scienece

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 analyser

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 AABB 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 to 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

Isfehan

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
City
esfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0042
Email
alikiaiib@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
Street address
hezarjarib
City
esfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0042
Email
haghjoo.sh@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
Mohammad Bagherniya
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
hezarjarib
City
esfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3620 1293
Email
bagherniya@nutr.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Bagherniya
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
hezarjarib
City

esfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3620 1293

Email

bagherniya@nutr.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

saeed abbasi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Practitioner

Street address

hezarjarib

City

esfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3620 1293

Email

s_abbasi@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

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