# 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

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Iran (Islamic Republic of)

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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 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
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Shaghayegh Haghjoo
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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**
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**Other areas of specialty/work**
Nutrition
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## Person responsible for scientific inquiries

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## 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**

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**Other areas of specialty/work**

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**Province**

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8174673461

**Phone**

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**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**