

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Investigating the effect of Curcumin supplementation on mortality rate and clinical status in patients with trauma hospitalized in the intensive care unit

#### Protocol summary

##### Study aim

Investigating the effect of Curcumin supplementation on mortality rate and clinical status in patients with trauma hospitalized in the intensive care unit

##### Design

Triple-blind parallel randomized clinical trial with control group, phase 2, on 327 patients. We will use the website ([www.sealedenvelope.com](http://www.sealedenvelope.com)) for randomization.

##### Settings and conduct

Traumatic ICU admitted patients in Bahonar hospital in Kerman, with mentioned inclusion criteria, will be enrolled to this study after informed consent. They will be divided into 2 groups of intervention and 1 control group. The duration of intervention will be 7 days and it will be administered by dissolving the powder inside capsule in gavage solution.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Minimum age of 12 years old, ICU admission due to trauma, Sign informed consent by the patients or his legal guardian, Oral or enteral nutrition (nasogastric or orogastric tube). Exclusion Criteria: Pregnancy or breast feeding, Severe and active bleeding, Re-hospitalization or refer from other hospitals/ICUs, History of obstructive biliary disorders, Allergy to Turmeric.

##### Intervention groups

First intervention group: Curcumin tablet twice daily (each tablet contain 500 mg Curcumin plus 5mg Piperine) for 7 days made by Sami-Sabinsa Group Limited. Second intervention group: Curcumin tablet once a day (contain 500 mg Curcumin plus 5mg Piperine) plus placebo once a day (for 7 days) made by Sami-Sabinsa Group Limited. Control group: placebo twice daily for 7 days made by Sami-Sabinsa Group Limited.

##### Main outcome variables

Primary outcomes: 8day ICU-mortality and 30-day and 60-days mortality. Secondary outcomes: duration of

hospitalization, stay at ICU, and mechanical ventilation, GCS, APACHE, SOFA, mNUTRIC, CBC, BS, Na, K, ALT, AST, BUN, Cr, CRP, CPK, 120-and 180-day mortality

#### General information

##### Reason for update

Revise outcomes (add new secondary outcomes)

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130829014521N21**

Registration date: **2023-04-23, 1402/02/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2026-05-18, 1405/02/28**

Update count: **2**

##### Registration date

2023-04-23, 1402/02/03

##### Registrant information

###### Name

Amirhossein Sahebkar

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

sahebkar@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-03-21, 1402/01/01

##### Expected recruitment end date

2025-07-23, 1404/05/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effect of Curcumin supplementation on mortality rate and clinical status in patients with trauma hospitalized in the intensive care unit

**Public title**

The effect of Curcumin supplementation on mortality rate and clinical status in patients with trauma

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Minimum age of 12 years old ICU admission due to trauma Sign informed consent by the patients or his legal guardian Oral or enteral nutrition (nasogastric or orogastric tube)

**Exclusion criteria:**

Pregnancy or breast feeding Severe and active bleeding Re-hospitalization or refer from other hospitals or ICUs History of obstructive biliary disorders Allergy to Turmeric

**Age**

From **12 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **327**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization was conducted using the block sizes of 3, 6, and 9 with the help of randomization websites ([www.sealedenvelope.com](http://www.sealedenvelope.com)). Once A/B/C codes were generated, a list including 327 numbers corresponding to the A/B/C codes will be prepared by a third party and given to the researcher. Someone outside of the research team will pack and label the drugs (from 1 to 327). After obtaining informed consent from eligible participants, one pack of drugs is taken and used accordingly. After completing the data gathering process, each number and its corresponding A/B/C codes will be entered into the software for analysis. Upon completion of the analysis, the A/B/C codes will be decoded.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

As mentioned before, after randomization, the patients place in three groups of A/B/C and received the products similar in shape and color (blinding of participants). The physician/nurse who will give the products to participants, received the boxes of the products with randomized codes (so the physician is blind too). The information of the patients and theirs treatment groups will be written with randomized codes (A/B/C) on datasheets (the blinding of the assessor). Data will be entered to the SPSS software with codes (the blinding of the analyzer).

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Mashhad University of Medical Sciences

**Street address**

Ghoreshi Building, Daneshgah Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138813944

**Approval date**

2023-03-04, 1401/12/13

**Ethics committee reference number**

IR.MUMS.REC.1401.403

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

Trauma

**ICD-10 code**

-

**ICD-10 code description**

-

**Primary outcomes****1****Description**

Mortality during the intervention in the ICU (8-day ICU mortality)

**Timepoint**

During the first 8-day ICU stay

**Method of measurement**

Observation and record in checklist

**2****Description**

60-days mortality

**Timepoint**

Mortality during the 60 days after entering to the study

**Method of measurement**

The information will be obtained by phone call.

**3****Description**

30-days mortality

**Timepoint**

Mortality during the 30 days after entering to the study

**Method of measurement**

The information will be obtained by phone call.

**Secondary outcomes****1****Description**

Duration of hospitalization

**Timepoint**

Duration of hospitalization will be recorded at the end of the study period.

**Method of measurement**

Observation (record in checklist)

**2****Description**

Duration of mechanical ventilation

**Timepoint**

Duration of mechanical ventilation will be recorded at the end of the intervention period.

**Method of measurement**

Observation (record in checklist)

**3****Description**

GCS (Glasgow coma scale)

**Timepoint**

Before and after the intervention period (7 days)

**Method of measurement**

Summing the scores of eye opening, verbal response and motor response.

**4****Description**

APACHE II(Acute Physiology and Chronic Health Evaluation)

**Timepoint**

Before and after the intervention (7 days)

**Method of measurement**

According to scoring system (APACHE is a severity-of-disease classification system that estimates mortality

based on a number of laboratory values and patient signs taking both acute and chronic disease into account. This score will be calculated based on the guidelines and recorded in the checklist).

**5****Description**

SOFA (Sequential Organ Failure Assessment)

**Timepoint**

Before and after the intervention (7 days)

**Method of measurement**

According to scoring system (SOFA score is a scoring system that assesses the performance of several organ systems in the body).

**6****Description**

Modified nutrition risk in critically ill (mNUTRIC) score

**Timepoint**

Before and after the intervention (7 days)

**Method of measurement**

According to scoring system (mNUTRIC is used to assess the nutrition risk in critically ill patients. This score estimates the risk according to some variables such as age, the number of comorbidities, hospitalization days, etc. This score will be calculated based on the guidelines and recorded in the checklist).

**7****Description**

Complete blood count (CBC)

**Timepoint**

Before and after the intervention period (7 days)

**Method of measurement**

Blood test

**8****Description**

Blood sugar (BS)

**Timepoint**

Before and after the intervention period (7 days)

**Method of measurement**

Blood test

**9****Description**

Concentration of sodium (Na) in the blood

**Timepoint**

Before and after the intervention period (7 days)

**Method of measurement**

Blood test

**10****Description**

Concentration of Potassium (K) in the blood

**Timepoint**

Before and after the intervention period (7 days)

**Method of measurement**

Blood test

**11****Description**

Liver enzymes including aspartate transaminase (AST) and alanine transaminase (ALT)

**Timepoint**

Before and after the intervention period (7 days)

**Method of measurement**

Blood test

**12****Description**

Blood urea nitrogen (BUN)

**Timepoint**

Before and after the intervention period (7 days)

**Method of measurement**

Blood test

**13****Description**

Creatinine

**Timepoint**

Before and after the intervention period (7 days)

**Method of measurement**

Blood test

**14****Description**

C-Reactive Protein (CRP)

**Timepoint**

Before and after the intervention period (7 days)

**Method of measurement**

Blood test

**15****Description**

Length of stay in ICU

**Timepoint**

Length of stay in ICU will be recorded at the end of the study period.

**Method of measurement**

Observation (record in checklist)

**16****Description**

Creatine phosphokinase (CPK)

**Timepoint**

Before and after the intervention period (7 days)

**Method of measurement**

Blood test

**17****Description**

120-day mortality

**Timepoint**

Mortality during the 120 days after entering to the study

**Method of measurement**

The information will be obtained by phone call

**18****Description**

180-day mortality

**Timepoint**

Mortality during the 180 days after entering to the study

**Method of measurement**

The information will be obtained by phone call

**Intervention groups****1****Description**

Intervention group 1: Curcumin tablet twice daily (each tablet contain 500 mg Curcumin plus 5mg Piperine made by Sami-Sabinsa Group Limited) for 7 days.

**Category**

Treatment - Drugs

**2****Description**

Intervention group 2: Curcumin tablet once a day (contain 500 mg Curcumin plus 5mg Piperine made by Sami-Sabinsa Group Limited) plus placebo tablet (made by Sami-Sabinsa Group Limited) once a day for 7 days

**Category**

Treatment - Drugs

**3****Description**

Control group: Placebo (microcrystalline cellulose) twice daily (similar to Curcumin tablet in shape, size and color) made by Sami-Sabinsa Group Limited for 7 days

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Bahonar Hospital

**Full name of responsible person**

Narges Ashraf Ganjooei

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## Sponsors / Funding sources

### 1

#### Sponsor

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**Full name of responsible person**  
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vcresearch@mums.ac.ir

#### Grant name

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

#### Title of funding source

Mashhad 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**  
Mashhad University of Medical Sciences

**Full name of responsible person**  
Amihossein Sahebkar

**Position**  
Associate professor

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Pharmaceutical biotechnology

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School of Pharmacy, University Campus, Azadi Square

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## **Sharing plan**

### **Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

### **Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

### **Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

## **Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

### **Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

### **Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

### **Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available