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) 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

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Iran (Islamic Republic of)

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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). 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 (Glascow 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
Street address
Shahid Bahonar Hospital, Qaraney Street
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
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
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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