Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of curcumin supplementation on inflammatory factors and prognosis in septic ICU patients

Protocol summary

Study aim
1- The effect of enteral curcumin on ICU admission days in septic patints 2- The effect of curcumin on SOFA score in ICU admitted septic patients 3- The effect of curcumin on ESR-CRP-TNF alpha- IL6 serum level in ICU admitted septic patients 4- The effect of curcumin on 10 days mortality rate in ICU admitted septic patients.

Design
Two arm parallel group blinded randomised clinical trial of 60 patients.

Settings and conduct
Dr. Shariaati Hospital , Tehran University of Medical Sciences, Tehran, iran

Participants/Inclusion and exclusion criteria
inclusion criteria: ICU admitted septic patient , APACHE score : 15-30, age : 18-75 years, ICU stay : at least 5 days , Entral feeding Exclusion criteria: entral feeding intolerance, estimation of death within 24 hours, pregnancy and breast feeding, vasopressor infusion

Intervention groups
Curcumin has been shown to have anti inflamatory effecs and can be used as a helpful complimentary medicine specially for criticlal patients admitted in ICU for sepsis and in this study the capsules used in intervention group . Maltodextrin is a white, starchy powder that manufacturers add into many foods to improve their flavor, thickness, or shelf life. Maltodextrin is a common ingredient in packaged foods tht will fill the placebo capsules in the control group.

Main outcome variables
illness severity improvement, reducing ICU staying days, mortality reduction in intervention group.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211023052849N2**
Registration date: **2022-03-09, 1400/12/18**
Registration timing: **registered_while_recruiting**

Last update: **2022-03-09, 1400/12/18**
Update count: **0**

Registration date
2022-03-09, 1400/12/18

Registrant information

Name
Arash Heroabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8490 2373

Email address
aheroabadi@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-06, 1400/09/15

Expected recruitment end date
2022-05-05, 1401/02/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of curcumin supplementation on inflammatory factors and prognosis in septic ICU patients

Public title
The effect of curcumin on septic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

عدم تحمل تغذیه انترال پیش بینی مرگ طی 24 ساعت بارداری و مقاوم به درمان mmHg شیردهی فشار سیستولیک کمتر از 90

Exclusion criteria:

entral feeding intolerance estimation of death in next 24 hours pregnancy and breast feeding systolic blood pressure less than 90 mm-Hg resistant to therapy

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization lists are computer-based by a statistician and the participants and project managers will be completely unaware (blind) about the intervention and control groups. Placebo capsules are identical capsules containing the same amount of maltodextrin. Both curcumin and placebo (Maltodexterin) capsules are produced by Arjuna Natural Extract, India. The concealments of supplements will be done by a third person, and the participants and investigators are not aware of the groups' assignments until the end of analysis.

Blinding (investigator's opinion)

Double blinded

Blinding description

Capsules are inside a sealed pocket with a specific code. Both the investigator and the nurse are unaware of the realation between the code and the type of capsule (curcumin or placebo)

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committee of Tehran University of Medical Sciences

Street address

No 506. Qods St, Keshavarz Blv, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1415983111

Approval date

2021-03-17, 1399/12/27

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.117

Health conditions studied

1

Description of health condition studied

sepsis

ICD-10 code

A41.9

ICD-10 code description

Sepsis with septicemia

Primary outcomes

1

Description

length of stay in ICU

Timepoint

daily

Method of measurement

patient documents

Secondary outcomes

1

Description

TNF-alpha

Timepoint

0, 5 days after intervention

Method of measurement

ELISA

2

Description

IL-6

Timepoint

0, 5 days after intervention

Method of measurement

ELISA

3

Description

ESR

Timepoint

0, 5 days after intervention

Method of measurement

ELISA

4

Description
crp
Timepoint
0, 5 days after intervention
Method of measurement
ELISA

5

Description
CBC
Timepoint
0, 5 days after intervention
Method of measurement
-

Intervention groups

1

Description
Intervention group: curcumin
Category
Treatment - Devices

2

Description
Control group: placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati hospital
Full name of responsible person
Arash Heroabadi
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Phone
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Email
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Arash Heroabadi
Position
assistant professor
Latest degree
Specialist
Other areas of specialty/work
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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
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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Data collected for the primary outcomes will be shared.

When the data will become available and for how long
access starting after publication

To whom data/document is available
Our data will only be available for people working in academic institutions.

Under which criteria data/document could be used
Our data of the study will only be accessible for conducting Meta-analysis.

From where data/document is obtainable
To access the required data, the researchers can contact Dr. Arash Heroabadi: Email address:arash.heroabadi@gmail.com

What processes are involved for a request to access data/document
The applicants should provide a description of the propose of their Meta-analysis. That request will be assessed, and if we agree to the request, the data will be emailed.

Comments