

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 patients 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. Shariati 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 , Enteral feeding Exclusion criteria: enteral feeding intolerance, estimation of death within 24 hours, pregnancy and breast feeding, vasopressor infusion

Intervention groups

Curcumin has been shown to have anti-inflammatory effects and can be used as a helpful complementary medicine specially for critical 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 that 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 (Maltodextrin) 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 relation 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

Kargar Shomali

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Phone

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Arash Heroabadi

Street address

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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

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Safie

Position

Resident

Latest degree

Medical doctor

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

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