

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The Effect of curcumin on oxidative indices, inflammatory factors and Sequential Organ Failure Assessment Score in patients with systemic inflammatory response syndrome

Protocol summary

Study aim

1- Determining and comparing the effect of curcumin supplementation on oxidative indices in patients with systemic inflammatory response syndrome (SIRS). 2- Determining and comparing the effect of curcumin supplementation on inflammatory indicators in patients with SIRS. 3- Determining and comparing the effect of curcumin supplementation on the SOFA index in patients with SIRS

Design

In this study 40 patients aged 18-50 years with systemic inflammatory response syndrome (SIRS positive) are selected in ICU Participants are randomly assigned to RAS software by random block method in one of two groups of curcumin or a control group.

Settings and conduct

After selecting the samples from Imam Reza Tabriz Hospital, the patients are placed in one of two curcumin and control groups. On the first, fifth and tenth day of the study, the SOFA questionnaire, nutritional status will be completed for the patients. Also, 5 cc of blood will be taken from the patients

Participants/Inclusion and exclusion criteria

Inclusions criteria for the study: Critically ill ICU patients with APACHE II score of 15-30; Positive SIRS; Aged over 18 and under the age of 60 years; Hospitalization at least 10 days in ICU; Recipients of enteral nutrition formula; Exclusions criteria: Parenteral feeding; Intolerance to enteral feeding and gavage solution; Patient is waiting for death in the 24 future hourse; HIV positive patient; Pregnant and lactating women; Ileus; Mellitus diabetes; Short bowel syndrome; Pancreatitis; Immune disorders

Intervention groups

The intervention group (two 80 mg capsules) will receive 160 mg / day curcumin The control group will receive the usual formulation without supplementation.

Main outcome variables

1- Assessment of oxidative indices 2- Assessment of inflammatory factors 3. Assessment of SOFA index 4. Assessment of nutrition status 5. Assessment of biochemical factors

General information

Reason for update

Publishing some of the study results and updating the modified factors related to the disease

Acronym

coiss

IRCT registration information

IRCT registration number: **IRCT20110123005670N7**

Registration date: **2017-12-15, 1396/09/24**

Registration timing: **prospective**

Last update: **2023-08-21, 1402/05/30**

Update count: **1**

Registration date

2017-12-15, 1396/09/24

Registrant information

Name

Ali Tarighat-Esfanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

2018-11-19, 1397/08/28

Actual recruitment end date

2019-08-27, 1398/06/05

Trial completion date

2019-08-27, 1398/06/05

Scientific title

The Effect of curcumin on oxidative indices, inflammatory factors and Sequential Organ Failure Assessment Score in patients with systemic inflammatory response syndrome

Public title

The Effect of curcumin on patients with systemic inflammatory response syndrome

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Critically ill ICU patients with APACHE II score of 15-30; Positive SIRS; Aged over 18 and under the age of 60 years; Hospitalization at least 10 days in ICU; Recipients of enteral nutrition formula

Exclusion criteria:

Parenteral feeding; Intolerance to enteral feeding and gavage solution; Patient is waiting for death in the 24 future hour; HIV positive patient; pregnant and lactating women; Ileus; Mellitus diabetes; Short bowel syndrome; Pancreatitis; Immune disorders

AgeFrom **18 years** old to **60 years** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **40**Actual sample size reached: **40****Randomization (investigator's opinion)**

Randomized

Randomization description

With Using of RAS software in two groups of 20 people

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

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

Ethics Committee of Tabriz University of Medical Sciences

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Golghast Street

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5166614711

Approval date

2017-11-13, 1396/08/22

Ethics committee reference number

IR.TBZMED.REC.1396.762

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

Sepsis/At risk of sepsis

ICD-10 code

R65.1

ICD-10 code description

Systemic inflammatory response syndrome (SIRS) of non-infectious origin

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

Inflammation

Timepoint

First, fifth, and tenth day

Method of measurement

Interleukin 6 and tumor necrosis factor-alpha, Forkhead box P3, NLR family pyrin domain containing 3, interferon-gamma, and nuclear factor kappa B, high mobility group box 1, Interleukin 8, Interleukin 17 and Interleukin 22, Interleukin 10, presepsin, TLR4, ICAM- 1, VCAM-1 and PCT

2**Description**

Oxidative stress

Timepoint

First, fifth, and tenth day

Method of measurement

Total antioxidant capacity and malondialdehyde, Nrf2, SOD, GPX, BAX, BCL2

3**Description**

Sequential Organ Failure Assessment (SOFA)

Timepoint

First, fifth, and tenth day

Method of measurement

Questionnaire

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

Nutrition status

Timepoint

روز 1، 5 و روز 10

Method of measurement

Received calorie measuring

2**Description**

Biochemical factors

Timepoint

روز 1، 5 و روز 10

Method of measurement

Biochemistry kit

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

Intervention group: Two curcumin capsules(Sina Pharmaceutical Company) of 80 mg per day for ten days

Category

Treatment - Drugs

2**Description**

Control group: Common formulas

Category

N/A

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

Imam Reza Hospital

Full name of responsible person

Dr. Ata Mahmoodpour

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Vice-Dean for Research and Technology Tabriz University Of Medical Science

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**

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Ali Tarighat-Esfanjani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Name of organization / entity
Tabriz University of Medical Sciences

Trial results

Please tick if results have been published

Yes

Summary result posting date

2023-08-21, 1402/05/30

Table of baseline comparison

Participant flow diagram

Table of variable outcomes' results

Table of adverse events

First publication date

2020-04-28, 1399/02/09

Abstract of published paper

Introduction Sepsis is a severe reaction and excessive immune response to infection, which can lead to tissue damage, organ dysfunction, and death. This study aimed to investigate the protective effect of curcumin on inflammatory factors and clinical outcomes in patients with sepsis. Methods This randomized clinical trial was conducted on 40 patients with sepsis aged 18-55 years, who received 160 mg of nano curcumin supplement (two capsules 80 mg) or placebo (two

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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

No - There is not 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

Not applicable

capsules of placebo) via a nasogastric tube for 10 days. Sequential organ failure assessment (SOFA) was evaluated on days 1 and 10. Serum levels of inflammatory factors of procalcitonin (PCT), Interleukin- 6 (IL-6), tumor necrosis factor- α , (TNF- α), and high-sensitive C-reactive protein (hs-CRP) were measured before the beginning of the intervention and on days 5 and 10. Length of hospital stay, mortality rate, and mechanical ventilation duration was compared between groups. Results Serum levels of PCT ($p = 0.002$), IL-6 ($p = 0.012$), and TNF- α ($p = 0.026$) in the nano curcumin group on day 10 were significantly lower than in the placebo group. The duration of mechanical ventilation in the nano curcumin group was remarkably ($p = 0.038$) lower than in the placebo group. Also, the SOFA score significantly ($p = 0.005$) decreased in the intervention group compared to the placebo group. No significant difference was observed in the mean serum levels of hs-CRP, duration of the intensive care unit stay, and mortality rates between the study groups. Conclusions Our study indicated that nano curcumin could decrease the levels of inflammatory factors, duration of mechanical ventilation, and organ failure in critically ill patients.