

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Effect of curcumin on coagulation factors, anti-inflammatory factor and Simplified Acute Physiology Score II in patients with systemic inflammatory response syndrome

Protocol summary

Study aim

Determination and comparison of the effect of curcumin supplementation on coagulation factors (Protein C, PTT), anti-inflammatory factor (TGF- β 1) and simplified acute physiology score II (SAPS II) in the curcumin supplement group and control group in patients with systemic inflammatory response syndrome (SIRS)

Design

The present study is a randomized, single blinded clinical trial of 32 patients aged 18-60 years with SIRS in ICU. Samples were randomly assigned to RAS software in one of two groups of curcumin supplementation and control.

Settings and conduct

After selecting samples from Imam Reza Hospital in Tabriz, patients are placed in one of the two groups of curcumin supplement and control. During the intervention on the first, fifth and tenth day of the study, the SAPSII questionnaire will be completed and 5cc blood will be taken from patients to examine the factors.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Critically ill patients with Acute Physiology and Chronic Health Evaluation II (APACHE II) score of 15-30, Positive Systemic inflammatory response syndrome (SIRS), Age over 18 and under 60, At least 10 days hospitalization in ICU, Patients who received enteral nutrition formula
Exclusion criteria: Parenteral feeding, Enteral nutrition and gavage formula intolerance, Patients expected to die within the next 24 hours, HIV positive, Pregnancy and lactation, ileus, Immune disorder, Diabetes melitus, Short bowel syndrome, Pancreatitis

Intervention groups

The intervention group will receive (two 80-mg capsules), 160 miligram per day curcumin, at least 1 hour away from the patient's formula (to avoid possible food-drug interactions) with the received fluids, and the control

group will receive the usual formula without supplementation.

Main outcome variables

Assessment of coagulation factors (Protein C, PTT), anti-inflammatory factor (TGF- β 1), and SAPSII

General information

Reason for update

Acronym

cosirs

IRCT registration information

IRCT registration number: **IRCT20110123005670N27**

Registration date: **2019-02-24, 1397/12/05**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-24, 1397/12/05**

Update count: **0**

Registration date

2019-02-24, 1397/12/05

Registrant information

Name

Ali Tarighat-Esfanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 914 300 5895

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-26, 1397/10/05

Expected recruitment end date

2019-06-20, 1398/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of curcumin on coagulation factors, anti-inflammatory factor and Simplified Acute Physiology Score [?] in patients with systemic inflammatory response syndrome

Public title
Effect of curcumin on systemic inflammatory response syndrome

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Critically ill patients with APACHE II score of 15-30
 Positive SIRS Age over 18 and under 60 At least 10 days hospitalization in ICU Patients who received enteral nutrition formula
Exclusion criteria:
 Parenteral feeding Enteral nutrition and gavage formula intolerance Patients expected to die within the next 24 hours HIV positive patients Pregnant and lactating women ileus Immune disorder Diabetes melitus Short bowel syndrome Pancreatitis

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Using RAS software and random block method

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients participating in this study will not be aware of the supplementation of curcumin due to low alertness

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

Street address

Tabriz University of Medical Sciences, Golgasht street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2018-12-24, 1397/10/03

Ethics committee reference number

IR.TBZMED.REC.1397.762

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

Protein C

Timepoint

Day 1, 5 and 10 of intervention

Method of measurement

ELISA Kit

2

Description

Partial Thromboplastin time

Timepoint

Day 1, 5 and 10 of intervention

Method of measurement

ELISA kit

3

Description

Prediction of death

Timepoint

Day 1, 5 and 10 of intervention

Method of measurement

Simplified Acute Physiology Score questionnaire

4

Description

Transforming growth factor β 1

Timepoint

Day 1, 5 and 10 of intervention

Method of measurement

ELISA kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Two 80-mg capsules of nano-curcumin (Sina Pharmaceutical Company) per day for 10 days

Category

Treatment - Drugs

2

Description

Control group: entera meal formula (karen company) or blenderized formula (contain rice flour and meat or poultry and tomato or carrot or cucumber and olive oil or corn oil and apple or orange and yoghurt or powdered milk)

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr. Ata Mahmoodpour

Street address

Golgasht Street

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5166/15731

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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Golgasht street, Tabriz University Of Medical Science, Tabriz

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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

Deputy of Research and Technology of Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Ali Tarighat Esfajani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Ali Tarighat Esfanjani

Position

Assistant professor

Latest degree

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Full name of responsible person

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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