

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigation of the Effects of Curcumin Supplementation on Inflammatory, Oxidative stress and Adipokine Markers and Nutritional and Clinical status in Traumatic Brain Injury Patients Receiving Enteral Nutrition at Intensive Care Unit

Protocol summary

Study aim

Determining the effects of curcumin supplementation on inflammatory, oxidative stress and adipokines and nutritional and clinical status among traumatic brain injury patients receiving enteral nutrition hospitalized at the intensive care unit

Design

A randomized double blind placebo-controlled clinical trial

Settings and conduct

This study will be performed at ICU of Sina and Shohada hospital. The researchers and patients and their first degree relatives will be blinded about the kind of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients aged 18-65 years old with Glasgow Coma Score (GCS) equal to 7 or more who are admitted ICU due to Traumatic Brain Injury (TBI) and the consent form has been signed by themselves or their first degree relatives will be considered for the study.
Exclusion criteria: Pregnancy and lactation; Septic patients who are hemodynamically and metabolically unstable; Patients who are not allowed to receive nutritional support in the first 24-48 hours; History of any kind of autoimmune disorders.

Intervention groups

There will be two groups including curcumin and placebo that receive 500 mg curcumin or placebo daily for 7 days.

Main outcome variables

Inflammatory markers; oxidative stress markers; adipokines; NUTRIC score; SOFA score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180619040151N1**

Registration date: **2018-09-18, 1397/06/27**

Registration timing: **prospective**

Last update: **2019-10-01, 1398/07/09**

Update count: **2**

Registration date

2018-09-18, 1397/06/27

Registrant information

Name

Abdolreza Norouzy

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2382

Email address

norouzya@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-02, 1397/08/11

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the Effects of Curcumin Supplementation on Inflammatory, Oxidative stress and Adipokine Markers and Nutritional and Clinical status in Traumatic Brain Injury Patients Receiving Enteral Nutrition at Intensive Care Unit	Used Assignment Parallel Other design features
Public title Investigation of the effects of curcumin in patients hospitalized at intensive care unit	Secondary Ids empty
Purpose Prevention	Ethics committees
Inclusion/Exclusion criteria Inclusion criteria: Being at the age of 18-65 years old Admission to ICU due to head trauma Signing consent form by patient or first degree relatives Glasgow coma score equal to 7 or more Exclusion criteria: Pregnancy and lactation Septic patients who are hemodynamically and metabolically unstable Patients who are not allowed to receive nutritional support in the first 24-48 hours History of any kind of autoimmune disorders History of cancer Chemotherapy and radiotherapy within previous month Receiving positive inotropic agents including dopamine, dobutamine and epinephrine History of any kind of liver failures Severe and active hemorrhage History of AIDS History of known food allergy Morbid obesity (BMI>40)	1 Ethics committee Name of ethics committee Ethics Committee of Tehran University of Medical Sciences Street address Central Office of Tehran University of Medical Sciences, corner of Qods street, Keshavarz Blvd City Tehran Province Tehran Postal code 1417653761
Age From 18 years old to 65 years old	Approval date 2018-05-05, 1397/02/15
Gender Both	Ethics committee reference number IR.TUMS.VCR.REC.1397.141
Phase 3	2
Groups that have been masked • Participant • Investigator • Outcome assessor • Data analyser	Ethics committee Name of ethics committee Ethics committee of Semnan University of Medical Sciences Street address Basij Blvd, Central Office of Semnan University of Medical Sciences City Semnan Province Semnan Postal code 99951- 35198
Sample size Target sample size: 52	Approval date 2018-06-12, 1397/03/22
Randomization (investigator's opinion) Randomized	Ethics committee reference number IR.SEMUMS.REC.1397.001
Randomization description In this study, stratified randomization will be used. First, the participants will be stratified based on age (18-40 or 40-65 years old) ,sex (male or female) and APACHEII score (0-35 or 35-71) and then they will be allocated to intervention or placebo group based on the blocks of size 4. Blocks of size 4 have 6 modes (AABB, ABAB, ABBA, BBAA, BAAB, BABA). These modes will be available to the relevant nurse and based on these blocks, the patients will be placed in the intervention or placebo group.	Health conditions studied 1 Description of health condition studied Traumatic Brain Injury ICD-10 code S06.2 ICD-10 code description Diffuse traumatic brain injury
Blinding (investigator's opinion) Double blinded	
Blinding description The supplements (curcumin or placebo) used in this study are exactly similar in appearance. Moreover, neither researcher nor patients or their first degree relatives will not know the kind of supplements and supplements will be administered by the relevant nurse.	
Placebo	

Primary outcomes

1

Description

Serum concentration of IL-6

Timepoint

The first and 8th day of the study

Method of measurement

By ELISA method

2

Description

Serum concentration of TNF- α

Timepoint

The first and 8th day of the study

Method of measurement

By ELISA method

3

Description

Serum concentration of MCP-1

Timepoint

The first and 8th day of the study

Method of measurement

By ELISA method

4

Description

Serum concentration of CRP

Timepoint

The first and 8th day of the study

Method of measurement

By Immunoturbidimetry method

5

Description

Serum concentration of glutathione peroxidase

Timepoint

The first and 8th day of the study

Method of measurement

By Colorimetric method

6

Description

Serum concentration of superoxide desmutase

Timepoint

The first and 8th day of the study

Method of measurement

By Colorimetric method

7

Description

Serum concentration of leptin

Timepoint

The first and 8th day of the study

Method of measurement

By ELISA method

8

Description

Serum concentration of adiponectin

Timepoint

The first and 8th day of the study

Method of measurement

By ELISA method

9

Description

NUTRIC score

Timepoint

The first and 8th day of the study

Method of measurement

By questionnaire

10

Description

SOFA score

Timepoint

The first and 8th day of the study

Method of measurement

By questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group will receive 500 mg curcuminoids in combination with 5 mg piperine (produced by Sabinsa company) added to enteral nutrition formula for 7 days. Because of low bio availability of curcuminoids, piperine will be added to increase it.

Category

Prevention

2

Description

Control group: This group will receive matched placebo (lactose) added to enteral nutrition formula for 7 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Hoda Sadat Zahedi

Street address

Before Hasan Abad Square, Imam Khomeini Street

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8500

Email

hosp_sina@sina.tums.ac.ir

Web page address

http://sinahospital.tums.ac.ir/

2

Recruitment center

Name of recruitment center

Shoda Tajrish Hospital

Full name of responsible person

Hoda Sadat Zahedi

Street address

Tajrish Sq., Tehran, Iran

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Province

Tehran

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1989934148

Phone

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Web page address

http://shmc.sbmu.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad Ali Sahraian

Street address

6th floor, Central buliding of Tehran University of Medical Sciences, Corner of Qods st, Keshavarz blvd

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Email

tums_edu@tums.ac.ir

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

72

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

2

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr Parviz Kokhaei

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

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Semnan

Province

Semnan

Postal code

35198 - 99951

Phone

+98 23 3344 1022

Email

rds@semums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Semnan University of Medical Sciences

Proportion provided by this source

28

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

Hoda Sadat Zahedi

Position

PhD candidate in Nutritional Sciences

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

No. 44, Shahid Hojjat doust Alley, Naderi St.,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Abdolreza Norouzy

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Nutrition

Street address

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hoda Sadat Zahedi

Position

PhD candidate of Nutritional Sciences

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

No. 44, Shahid Hojjat doust Alley, Naderi St.,
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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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