Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

The effect of seven-strain probiotic supplementation on some of the Thelpers, ICAM, VCAM, prooxidant-antioxidant balance, oxidative stress and inflammatory biomarkers and nutritional status in patients with head trauma admitted to intensive care unit: a randomized controlled clinical trial

Protocol summary

Study aim
The effect of seven-strain probiotic supplementation on some of the Thelpers, ICAM, VCAM, prooxidant-antioxidant balance, oxidative stress and inflammatory biomarkers and nutritional status in patients with head trauma admitted to intensive care unit

Design
Randomized, double-blinded, controlled trial

Settings and conduct
This study will be conducted on 46 patients with traumatic brain injury, admitted to the intensive care unit of Imam Reza Hospital and Shohada Hospital. Patients will be randomized into 2 equal groups of supplement or placebo and will receive probiotic and placebo respectively for 2 weeks.

Participants/Inclusion and exclusion criteria
- Age 60-18 years of both sexes - GCS <8 - Nutrition through the nasal tube - stomach - Willingness to cooperate by obtaining the consent of first-degree relatives -Having an APACHE II score of 15–30

Intervention groups
Participants will be randomized into two groups of 23 people: intervention group (four probiotic capsules daily (every 6 hours)) or placebo group (four placebo capsules daily (every 6 hours)) and will use the supplement or placebo for 2 weeks.

Main outcome variables
Th-17, T-regulatory, Th10, TGF-β, IL-6, IL-1β, length of hospital stay, Damping rate, Respiratory tract infection, Weight, BMI, level of consciousness, Illness severity

General information

Reason for update
Addition of factors related to prooxidant and antioxidant indices

Acronym

IRCT registration information
IRCT registration number: **IRCT20100209003320N18**
Registration date: **2020-09-07, 1399/06/17**
Registration timing: **prospective**

Last update: **2024-11-14, 1403/08/24**
Update count: **3**

Registration date
2020-09-07, 1399/06/17

Registrant information

Name
Mehrangiz Ebrahimi mamagani

Name of organization / entity
Health & Nutrition faculty of Tabriz university of medical sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-20, 1399/06/30

Expected recruitment end date
2022-08-19, 1401/05/28

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of seven-strain probiotic supplementation on some of the Thelpers, ICAM, VCAM, prooxidant-antioxidant balance, oxidative stress and inflammatory biomarkers and nutritional status in patients with head trauma admitted to intensive care unit: a randomized controlled clinical trial

Public title
Effect of probiotic on immune system and oxidative stress in intensive care unit patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 60 to 18 years Low level of consciousness (GCS <8) Nutrition through the nasal - stomach tube Willingness to cooperate by obtaining the consent of first-degree relatives Patients receiving gavage Presence in the intensive care unit for at least 14 days Having an APACHE II score of 15–30
Exclusion criteria:
Pregnancy- Breastfeeding Parental nutrition (more than two days) Taking immunosuppressive medications Unstable hemodynamics Intestinal obstruction; intestinal ischemia; short bowel syndrome
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
46 eligible patients will be randomly allocated to intervention and placebo groups using a software generated random permuted blocks. The generated random sequence will be kept in a protected location and administered by an independent third party who is blind to the trial throughout the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the investigators, patients, those responsible for patient enrollment, administration of the intervention, and assessors (nurses) will be blinded to the type of the supplement (probiotic or placebo) received by each group. The person responsible for preparing the supplement capsules (who is completely unrelated to the study) will be asked to assign a three-digit code to each of the two capsules (probiotic and placebo) and keep the codes for himself until the end of the study and data analysis.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The Research Ethics Committee of Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences, Attar Neishabouri Ave, Golgasht St
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Approval date
2020-08-10, 1399/05/20
Ethics committee reference number
IR.TBZMED.REC.1399.503

Health conditions studied

1

Description of health condition studied
Head Trauma
ICD-10 code
G44.31
ICD-10 code description
Acute post-traumatic headache

Primary outcomes

1

Description
Th-17, T-regulatory, Th10 cells
Timepoint
Beginning and end of the trial
Method of measurement
Flowcytometry

2

Description

Duration of hospitalization and rate of attenuation

Timepoint

Daily

Method of measurement

Observation and questionnaire

3

Description

Respiratory tract infection

Timepoint

Beginning and end of the trial

Method of measurement

Sputum Culture

4

Description

Serum levels of TGF-β

Timepoint

Beginning and end of the trial

Method of measurement

ELISA

5

Description

Serum levels of IL-6

Timepoint

Beginning and end of the trial

Method of measurement

ELISA

6

Description

Serum levels of IL-1β

Timepoint

Beginning and end of the trial

Method of measurement

ELISA

7

Description

Level of consciousness and severity of the disease

Timepoint

Daily

Method of measurement

GCS , APACHE and SOFA Questionnaire

8

Description

Weight

Timepoint

Beginning and end of the trial

Method of measurement

Calculation based on formula

9

Description

Body mass index

Timepoint

Beginning and end of the trial

Method of measurement

Calculation based on formula

Secondary outcomes

1

Description

Energy, macronutrients and antioxidant nutrients (vitamins A, E, C, selenium, zinc and copper) intake

Timepoint

Beginning and end of the trial

Method of measurement

Food record (gavage) - Nutritionist 4 software

2

Description

Intercellular adhesion molecule-1 (ICAM-1)

Timepoint

Beginning and end of the trial

Method of measurement

ELISA

3

Description

Vascular cell adhesion molecule 1 (VCAM-1)

Timepoint

Beginning and end of the trial

Method of measurement

ELISA

4

Description

Pro-oxidant-Antioxidant Balance (PAB)

Timepoint

Beginning and end of the trial

Method of measurement

ELISA

5

Description

Total antioxidant capacity (TAC)

Timepoint

Beginning and end of the trial

Method of measurement

Spectrophotometric method

6

Description

Malondialdehyde (MDA)

Timepoint

Beginning and end of the trial

Method of measurement

Spectrophotometric method

7

Description
Nitric oxide (NO)
Timepoint
Beginning and end of the trial
Method of measurement
ELISA

8

Description
Arylesterase (ARE) activity
Timepoint
Beginning and end of the trial
Method of measurement
Spectrophotometric method

Intervention groups

1

Description
Intervention group: Patients in this group will receive a probiotic supplement for 14 days. The supplement is: a capsule containing seven types of probiotics (produced by Zist takhmir Company made in Iran) and consumed four times a day (every 6 hours).
Category
Treatment - Drugs

2

Description
Control group: Patients in this group will receive a placebo for 14 days. Placebo contains maltodextrin (product of Zist takhmir Company made in Iran) and will be consumed four times a day (every 6 hours).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital and Shohada Hospital
Full name of responsible person
Mehrangize Ebrahimi mamagani
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Sponsors / Funding sources

1

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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?
Yes
Title of funding source
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
Mehrangiz Ebrahimi Mamagani
Position
Professor of Nutritional Sciences
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is 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 12 months after publication
To whom data/document is available
The data will only be available for people working in academic institutions.
Under which criteria data/document could be used
The data of the present study will only be accessible by other researchers, for conducting meta-analysis.
From where data/document is obtainable
Dr. Mehrangize Ebrahimi mamagani - Email: ebrahimimamagani@tbzmed.ac.ir- Tel: 00989141005681
What processes are involved for a request to access data/document
The applicant should provide a brief description of the aims and methods of his his Meta-analysis. His request will be assessed and, if agreed, the data will be emailed to the applicant. All these procedures will take no longer than 15 days.
Comments