Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of oral trehalose on inflammatory factors, oxidative stress and nutritional and clinical status in patients with traumatic head injury receiving enteral nutrition- a pilot study

Protocol summary

Study aim

To determine the effect of oral trehalose on inflammatory markers, oxidative stress, nutritional, and clinical status in patients with traumatic head injury receiving antral nutrition admitted to the intensive care unit.

Design

Clinical trial, with parallel groups, double-blind, randomized, phase 3-2 on 20 patients, block randomization method is used

Settings and conduct

Intensive care unit of hospitals in Mashhad.The similarity between medicine and placebo in terms of color, size, and smell, lack of knowledge of participants about the type of reception. Three blood samples (at the beginning, 6th, and 12th day of the study) 10 cc of venous blood sample is taken from the patient. During the day, they will receive standard hospital gavage.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with head trauma in the intensive care unit with stable hemodynamic and metabolic conditions who have GCS≥7 and antral nutrition and tend to participate in the study and do not tolerate foods containing trehalose such as mushrooms. No entry criteria: Patients with head trauma who have been on Nil Per Os (NPO) for more than 48 hours (not allowed to receive food), transferred to other ICUs after one week of hospitalization Have an underlying background (cancer, autoimmune diseases, congenital metabolic diseases), are pregnant or breastfeeding

Intervention groups

Intervention: Participants will be randomized to the intervention group or control group. During 12 days, patients in the intervention group will receive 30 grams of trehalose instead as a part of the carbohydrate of daily gavage. Their gavages will be administered by the bolus method.

Main outcome variables

CRP, IL6, MDA, SOD, Pro oxidant antioxidant balance, Glutathione, Total antioxidant capacity

General information

Reason for update

Change in sections

Acronym

IRCT registration information

IRCT registration number: **IRCT20210508051223N1**
Registration date: **2021-07-26, 1400/05/04**
Registration timing: **prospective**

Last update: **2022-05-08, 1401/02/18**
Update count: **3**

Registration date

2021-07-26, 1400/05/04

Registrant information

Name

Moazzameh Ghorbani Dehbalaei

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral trehalose on inflammatory factors, oxidative stress and nutritional and clinical status in patients with traumatic head injury receiving enteral nutrition- a pilot study

Public title

Evaluation of the effect of oral trehalose in patients with traumatic head injury in ICU

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Critically ill TBI patients admitted to ICU Stable hemodynamic and metabolic conditions in the first 24-48 h GCS≥7 Having antral feeding Lack of intolerance to food sources containing trehalose such as mushroom Willingness to cooperate and sign the informed consent form after full knowledge of the objectives and method of the study by the individual or legal guardian 18 year ≤ age ≤ 65 year

Exclusion criteria:

Patients with head trauma who have been on Nil Per Os (NPO) for more than 48 hours (not allowed to receive food). Head trauma patients receiving parenteral nutrition (TPN). Patients who are transferred from other ICUs after 1 week. Having a history of cancer, autoimmune diseases, and congenital metabolic diseases. Pregnancy and lactation.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is performed by stratified permuted block randomization method, with block size equal to 4. The allocation ratio is 1:1. Using the site www.sealedenvelope.com, a random sequence of five blocks will be generated, each containing four patients. The classification is based on age (18-65), gender (Male/Female), and APACHE II score (0 to 35 and 35 to 71) using quadruple blocks. The specific code for the participants and their treatment group is placed in different envelopes from 1 to 20. Upon the arrival of each eligible volunteer, informed consent will be obtained and then the first envelope will be opened, and its treatment group is determined. Allocation concealment will be considered using opaque-sealed sequentially numbered envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

For proper blindness, the drug and placebo will be exactly the same in color, size, and odor.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Deputy of Research and Technology, Ghorashi Building, next to Hoveyzeh Cinema, Dneshgah Street

City

Mashhad

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Razavi Khorasan

Postal code

9138813944

Approval date

2021-05-31, 1400/03/10

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.113

Health conditions studied

1

Description of health condition studied

Trauma / head injury. Intracranial injury that involves brain damage

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Serum level changes of c-reactive protein (CRP)

Timepoint

At the beginning of the study, 6th, and 12th day

Method of measurement

Special measuring kit

2

Description
Serum level changes of Interleukin 6 (IL-6)
Timepoint
At the beginning of the study, 6th, and 12th day
Method of measurement
Special measuring kit

3

Description
Serum level changes of Malondialdehyde (MDA)
Timepoint
At the beginning of the study, 6th, and 12th day
Method of measurement
Special measuring kit

4

Description
Serum level changes of superoxide dismutase (SOD)
Timepoint
At the beginning of the study, 6th, and 12th day
Method of measurement
Special measuring kit

5

Description
Serum level changes of total antioxidant capacity (TAC)
Timepoint
At the beginning of the study, the 6th, and 12th day
Method of measurement
Special measuring kit

6

Description
Pro oxidant antioxidant balance (PAB) in the Serum level
Timepoint
At the beginning of the study, 6th, and 12th day
Method of measurement
Laboratory testing with a previously known scientific method

7

Description
Serum level changes of Glutathione (GSH) changes
Timepoint
At the beginning of the study, 6th, and 12th day
Method of measurement
Special measuring kit

Secondary outcomes

1

Description
Blood sugar
Timepoint
Daily
Method of measurement
Glucometer

2

Description
blood pressure
Timepoint
Daily
Method of measurement
Barometer

3

Description
Lipid profile
Timepoint
Weekly
Method of measurement
Special kit

4

Description
Sequential Organ Failure Assessment (SOFA) criteria
Timepoint
Daily
Method of measurement
Questionnaire

5

Description
The Acute Physiology and Chronic Health Evaluation (APACHE II) criteria
Timepoint
At the beginning of the study ,6th, and 12th day
Method of measurement
APACHE II questionnaire

6

Description
Glasgow Coma Scale (GCS)
Timepoint
Daily
Method of measurement
Questionnaire (Scoring system)

7

Description
28-day mortality
Timepoint
28 days after admission to the ICU
Method of measurement
Check the patient's hospital electronic file information or check the patient's mortality by telephone.

8

Description
Nutrition Risk in the Critically ill score (NUTRIC score)
Timepoint

At the beginning of the study ,6th, and 12th day

Method of measurement

Questionnaire

Intervention groups

1

Description

The intervention group: During 12 days, patients in the intervention group will receive 30 grams of trehalose instead as a part of the carbohydrate of daily gavage. Their gavages will be administered by the bolus method

Category

Treatment - Other

2

Description

The control group: will receive standard isocaloric hospital gavage over 12 days.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Kamyab hospital

Full name of responsible person

Dr. Hamid Rezaei

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Fadaiyan-e-Islam Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Moazzameh Ghorbani Dehbalaei

Position

Student

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
Dr. Abdolreza Norouzi

Position
Associate Professor

Latest degree
Specialist

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Nutrition

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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