# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

14 Jul 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**

**Country**
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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https://h-kamyab.mums.ac.ir/

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Taqfadi

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vcresraech@mums.ac.ir

**Web page address**

https://v-research.mums.ac.ir/

**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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**Position**
Associate Professor

**Latest degree**
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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