

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of trehalose on inflammatory markers, stress oxidative, clinical symptoms and mortality in patients with head trauma: a randomized double-blind placebo controlled trial

Protocol summary

Study aim

The effect of trehalose on inflammatory markers, stress oxidative, clinical symptoms and mortality in patients with head trauma

Design

This is a randomized, double-blind, parallel-group, placebo-controlled clinical trial. Eighty participants were randomly assigned to receive daily trehalose supplementation (n = 40) or placebo (n = 40).

Settings and conduct

The present study is a double blind randomized parallel clinical trial. The target population includes people with traumatic brain injury in Al-Zahra Hospital. The samples will be randomly divided into intervention and placebo groups and will be studied for 7 days. Inflammatory markers, oxidative stress, clinical symptoms will be measured before and after the intervention, as well as 28, 60 and 90-day mortality and length of stay in the intensive care unit after the study. To double-blind this research, before starting the study, all the capsules are coded as A and B by someone other than the researcher.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18-65 years, diagnosis of head trauma by a physician and trauma diagnosis based on Injury Severity Score (ISS) between minor to severe, willingness to participation in the study and complete the informed consent form, gastrointestinal tract with normal function and intestinal nutritional criteria

Intervention groups

Intervention group will be fed by standard formula and two daily sachets (each sachet contains 5 grams trehalose; totally 10 gram trehalose in a day)

Main outcome variables

Serum CRP levels, erythrocyte sedimentation rate (ESR), NUTRIC score, SOFA score, APACHE II score, superoxide dismutase (SOD), malondialdehyde (MDA), total antioxidant capacity (TAC), 28-day, 60-day and 90-day

mortality, ICU length of stay, arterial blood gas (ABG) test.

General information

Reason for update

The study start date was mistakenly recorded. This study is prospective and was registered in the IRCT system after obtaining ethical approval and before its implementation.

Acronym

IRCT registration information

IRCT registration number: **IRCT20121216011763N55**

Registration date: **2022-11-07, 1401/08/16**

Registration timing: **prospective**

Last update: **2025-03-24, 1404/01/04**

Update count: **1**

Registration date

2022-11-07, 1401/08/16

Registrant information

Name

Gholamreza Askari

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2110

Email address

askari@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-05, 1404/02/15

Expected recruitment end date

2025-08-23, 1404/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of trehalose on inflammatory markers, stress oxidative, clinical symptoms and mortality in patients with head trauma: a randomized double-blind placebo controlled trial

Public title

Effect of trehalose in patients with head trauma

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18-65 years Diagnosis of head trauma by a physician and trauma diagnosis based on Injury Severity Score (ISS) between minor to severe Willingness to participate in the study and complete the informed consent form Gastrointestinal tract with normal function and intestinal nutritional criteria

Exclusion criteria:

Using parenteral nutrition People who do not tolerate enteral nutrition well and for any reason are supported by complete intravenous nutrition. Infection processes, diffuse intravascular coagulation and any inflammatory interactions that interfere with the intervention process. Unexpected adverse effects

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **80****Randomization (investigator's opinion)**

Randomized

Randomization description

Eligible participants will be randomly allocated in a ratio of 1:1 to either the intervention group or the control group. Randomization will be stratified according to sex (male vs. female), with the use of permuted block size of 4. group. For randomization the below website will be used: <https://www.sealedenvelope.com/simple-randomiser/v1/lists>

Blinding (investigator's opinion)

Double blinded

Blinding description

To run this study as a double -blinded study, before intervention, all sachets are encoded by a trained nutritionist, researchers will not be informed about randomization process until completion of data analyses (concealment). Trehalose and its placebos will in the

same form of package in terms of the size, color, shape, and the patients and researcher will not aware of the content of the pack until the end of trial

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

National Institute for Medical Research Development (NIMAD)

Street address

Besat street

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۶۹۳۱۱۱

Approval date

2021-09-12, 1400/06/21

Ethics committee reference number

IR.NIMAD.REC.1400.092

Health conditions studied**1****Description of health condition studied**

Brain damage with or without loss of consciousness for an unspecified period of time

ICD-10 code

S06.2

ICD-10 code description

Diffuse traumatic brain injury

Primary outcomes**1****Description**

Serum levels of High sensitive C-reactive protein (hs-CRP)

Timepoint

Beginning and end of the study

Method of measurement

ELISA method

2**Description**

Erythrocyte Sedimentation Rate (ESR)

Timepoint

Beginning and end of the study

Method of measurement

Enzymatic method

3**Description**

NUTRIC score

Timepoint

Beginning and end of the study

Method of measurement

By scoring a questionnaire including APACHE II and SOFA

4**Description**

Superoxide Dismutase (SOD)

Timepoint

Beginning and end of the study

Method of measurement

Blood sample

5**Description**

Malondialdehyde (MDA)

Timepoint

Beginning and end of the study

Method of measurement

Blood sample

6**Description**

Total antioxidant capacity (TAC)

Timepoint

Beginning and end of the study

Method of measurement

ELISA method

7**Description**

28-day, 60-day, and 90-day mortality

Timepoint

28-day and 90-day

Method of measurement

Use official statistics

8**Description**

Length of stay in the ICU and duration of hospitalization

Timepoint

End of the study

Method of measurement

By Using the patient's medical record

9**Description**

Arterial Blood Gas (ABG) test

Timepoint

Beginning and end of the study

Method of measurement

Blood Test

10**Description**

SOFA score

Timepoint

At the beginning and end of the intervention (7 days)

Method of measurement

By scoring the SOFA questionnaire

11**Description**

APACHE II Score

Timepoint

At the beginning and end of the intervention (7 days)

Method of measurement

By scoring the APACHE II questionnaire

12**Description**

Arterial Blood Gas (ABG) test

Timepoint

At the beginning and end of the intervention (7 days)

Method of measurement

Blood text

Secondary outcomes**1****Description**

cell blood count (CBC)

Timepoint

Beginning and end of the study

Method of measurement

Device analysis using cell counter device (hematology analyzer)

2**Description**

fasting blood sugar (FBS)

Timepoint

Beginning and end of the study

Method of measurement

Enzymatic methods

3**Description**

blood urea nitrogen (BUN)

Timepoint

Beginning and end of the study

Method of measurement

Biochemical test by enzymatic method

4

Description

Creatinine (Cr)

Timepoint

Beginning and end of the study

Method of measurement

Biochemical test by enzymatic method

5

Description

Alanine Transaminase (ALT)

Timepoint

Beginning and end of the study

Method of measurement

Enzymatic photometric method

6

Description

Aspartate Aminotransferase (AST)

Timepoint

Beginning and end of the study

Method of measurement

Enzymatic photometric method

7

Description

Weight

Timepoint

Beginning and end of the study

Method of measurement

Chumlea I formula

8

Description

Height

Timepoint

Beginning and end of the study

Method of measurement

Ulna length formula

9

Description

Mid Arm Circumferences (MAC)

Timepoint

Beginning and end of the study

Method of measurement

Non-elastic tape meters

Intervention groups

1

Description

Intervention group: Intervention group will be fed by standard formula and two daily sachets (each sachets contains 5 grams trehalose; totally 10 gram trehalose in a day)

Category

Treatment - Other

2

Description

Control group: control group will feed with standard formula and two sachets filledwith maltodextrin (each sachets contains 5 grams maltodextrin; totally 10 grams maltodextrin in a day)

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Al-Zahra hospital

Full name of responsible person

Ghulam Reza Askari

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Esfahan 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

Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Askari
Position
Professor
Latest degree
Ph.D.
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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

The collected deidentified for the primary outcome
measure only will be shared

When the data will become available and for how long

6 months after publication

To whom data/document is available

Available for people working in academic institutions

Under which criteria data/document could be used

To conduct similar studies

From where data/document is obtainable

askari@mui.ac.ir

What processes are involved for a request to access

data/document

The data will be sent to the person within one Month after receiving the request and reviewing the request.

Comments