Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 sachets 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 participation 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 completeintravenous nutrition. Infection processes, diffuse intravascular coagulation and any inflammatory interactions that interfere with the intervention process. Unexpected adverse effects
Age
From **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
Street address
Sofe Boulevard
City
Isfahan
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Isfehan
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8174673461
Phone
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Email
askari@mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza askari
Street address
Hezar jarib
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Isfahan
Province
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Postal code
8174673461
Phone
+98 31 3668 1378
Email
askari@mui.ac.ir
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.
Other areas of specialty/work
Nutrition
Street address
Department of Community Nutrition, Faculty of Nutrition, Isfahan University of Medical Sciences, Hezar Jerib St
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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