Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigation of the therapeutic effects of Intravenous Trehalose in mild cognitive impairment in the elderly

Protocol summary

Study aim
Investigation of the therapeutic effects of Intravenous Trehalose in mild cognitive impairment in the elderly

Design
Triple-blind parallel randomized clinical trial with control group, on 34 patients. (It should be noted that the participants, investigator, assessor, analyzer and Data and Safety Monitoring Board (DSMB) will be blinded to study groups.)

Settings and conduct
Elderly patients with mild cognitive disorder who will refer to psychiatrist in Ghaem/Ebnesina Hospitals or in private clinics in Mashhad, and meet the inclusion criteria, will be enrolled to this study after informed consent. They will be divided randomly into two groups of intervention (trehalose) and control (placebo). The study period will take 3 months. The mentioned outcomes will be assessed and compared between two groups at baseline and after 3 months.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Elderly with mild cognitive impairment (diagnosed by neuropsychiatrist), Age between 60 and 90, MOCA between 18 to 26, In case of using Donpezil or Rivastigmin, at least 3 months should be passed. Exclusion Criteria: Drug abuse, History of liver or renal failure, Major Depressive Disorder (MDD), Significant psychiatric disorders.

Intervention groups
Intervention group: Intravenous (IV) Trehalose (15 g per week) for 12 weeks by Dr.Rajabi Pharmaceutical company Control group: Intravenous (IV) Normal Salin per week for 12 weeks

Main outcome variables
Primary Outcomes: Mini-mental State Examination (MMSE) and Montreal Cognitive Assessment (MOCA). Secondary Outcomes: Fasting Blood Glucose (FBG), Electrolytes levels in serum (sodium, potassium).

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260625069941N1**
Registration date: **2026-07-20, 1405/04/29**
Registration timing: **prospective**

Last update: **2026-07-20, 1405/04/29**
Update count: **0**

Registration date
2026-07-20, 1405/04/29

Registrant information
Name
zanireh Salimi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-08-06, 1405/05/15
Expected recruitment end date
2028-08-05, 1407/05/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Investigation of the therapeutic effects of Intravenous Trehalose in mild cognitive impairment in the elderly

Public title
Investigation the effects of Trehalose in cognitive impairment in the elderly
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of mild cognitive impairment by a neuropsychiatrist Age between 60 to 90 In case of using Donpezil or Rivastigmin, at least 3 months should be passed MOCA between 18 and 26
Exclusion criteria:
Major depressive disorder Significant psychologic disorders Drug abuse Previous history of renal or liver failure
Age
From **60 years** old to **90 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **34**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization will be conducted using the block sizes of 2 and 4 with randomization websites such as sealedenvelope.com. After randomization, the type of treatment will be written with odds and even numbers (or A/B codes) in separate papers and placed in an opaque envelope or the paper will be wrapped so that no one can see inside the paper (allocation concealment). After obtaining informed consent from the participants, one paper will be taken in order and according to the noted code, the participants will be placed in one of the intervention or placebo groups.
Blinding (investigator's opinion)
Triple blinded
Blinding description
After randomization, the patients will be placed in two groups of A/B (or odds/even codes) and will receive the products similar in shape and color (blinding of participants). The physician who will give the products to participants, receive the boxes of the products with randomized codes (so the physician will be blind too). The information of the patients and theirs treatment groups will be written with randomized codes (A/B) (blinding of the assessor). Data will be entered to the SPSS software with codes (blinding of the analyzer). It should be noted that Data and Safety Monitoring Board (DSMB) will be blinded too.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Mashhad University of Medical Sciences
Street address
Dr.Kharazmi Educational Building, University Campus, Azadi Square
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2026-05-23, 1405/03/02
Ethics committee reference number
IR.MUMS.REC.1405.041

Health conditions studied

1

Description of health condition studied
Mild Cognitive Impairment
ICD-10 code
G31.84
ICD-10 code description
Mild cognitive impairment, so stated

Primary outcomes

1

Description
Assessment of Cognition by Mini-Mental State Examination (MMSE)
Timepoint
At baseline and after 12 weeks
Method of measurement
MMSE Questionnaire (This questionnaire consists questions about orientation, registration, attention and calculation, recall, language and praxis. The total score is 30.)

2

Description
Assessment of Cognition by Montreal Cognitive

Assessment (MOCA)

Timepoint

At baseline and after 12 weeks

Method of measurement

MOCA questionnaire (An interviewer is present during the completion of the questionnaire to provide guidance and clarify specific items. MOCA cosists some parts including Visuospatial/executive, Naming, Memory, Attention, Language, Abstraction, Delayed recall, and Orientation).

Secondary outcomes

1

Description

Fasting Blood Glucose (FBG)

Timepoint

At baseline and after 12 weeks

Method of measurement

Blood sample

2

Description

Electrolytes (Sodium and Potassium)

Timepoint

At baseline and after 12 weeks

Method of measurement

Blood sample

Intervention groups

1

Description

Intervention group: Intravenous (IV) Trehalose (15 g per week) for 12 weeks by Dr.Rajabi Pharmaceutical company

Category

Treatment - Drugs

2

Description

Control group: Intravenous (IV) Normal Salin per week for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Zanireh Salimi

Street address

Ghaem Hospital, Ahmad Abad Blvd.

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2

Recruitment center

Name of recruitment center

Ebnesina Hospital

Full name of responsible person

Zanireh Salimi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

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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

Zanireh Salimi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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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