Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

To assess the effect of trehalose on cognitive abillity in patients with Lewy body dementia and evaluation of key proteins in the protein interaction network of LBD

Protocol summary

Study aim
The aim of this study is to conduct a clinical trial of oral trehalose in people with Lewy body dementia and to find the mechanism of effectiveness of trehalose in these people using expression data of normal brain tissues and tissues of people with dementia with Lewy bodies using the network modeling method in systems biology.

Design
A controlled, triple-blind, randomized, phase 2 clinical trial on 60 patients.

Settings and conduct
Patients with Lewy body dementia with mentioned inclusion criteria, will be enrolled to this study after informed consent. By random allocation, they will be divided into intervention (trehalose) and placebo group. The duration of intervention will be 3 months. After the duration of intervention, the two groups will be compares for mentioned outcomes. It should be noted that as the products are similar in shape and color, the participants will be blinded to study groups. Moreover, as the treatment groups will be written in A/B codes in datasheets and in SPSS software, both the assessor and the analyzer will be blinded to study groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Individuals with Lewy body dementia who consent to participate in the study. Exclusion criteria: Suffering from atypical parkinsonism syndromes and Alzheimer's or other neurodegenerative diseases

Intervention groups
Trehalose intervention group will be administered 20 grams orally per day for up to three months; Placebo (sucrose) control group will be administered 20 grams orally per day.

Main outcome variables
Primary Outcome: In order to assess the cognitive impairment, the MMSE and MOCA tests will be performed at baseline and evaluated at the twelfth week of study.
Secondary Outcome: Serum level of alpha-synuclein.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250317065107N1**
Registration date: **2025-05-11, 1404/02/21**
Registration timing: **prospective**

Last update: **2025-05-11, 1404/02/21**
Update count: **0**

Registration date
2025-05-11, 1404/02/21

Registrant information

Name
Seyed Hamid Aghaee Bakhtiari

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
2025-05-22, 1404/03/01

Expected recruitment end date
2026-09-22, 1405/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
To assess the effect of trehalose on cognitive abillity in patients with Lewy body dementia and evaluation of key proteins in the protein interaction network of LBD

Public title
Assessment the effect of trehalose in patients with Lewy body dementia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Individuals with Lewy body dementia Individuals must consent to participate in the study
Exclusion criteria:
Having atypical parkinsonism syndromes Having Alzheimer Having other neurodegenerative diseases

Age
From **35 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals are randomly assigned to two groups: intervention and control using randomized blocks of 2 and 4 (using sealedenvelope.com). After randomization, the type of treatment is written in A/B codes in separate papers and placed in an opaque envelope or the paper will wrap so that no one can see inside the paper (random concealment). After obtaining informed consent from the participants, one paper will be taken in order and according to the noted code, the patient is place in one of the intervention or placebo groups.

Blinding (investigator's opinion)
Triple blinded

Blinding description
As mentioned before, after randomization, the patients place in groups of A/B and received the products similar in shape and color (blinding of participants). The information of the patients and theirs treatment groups will be written with randomized codes (A/B) on datasheets (the blinding of the assessor). Data will be entered to the SPSS software with codes (the blinding of the analyzer).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Mashhad University of Medical Sciences
Street address
Ghoreshi Building, Daneshgah Street
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Postal code
9138813944

Approval date
2025-01-22, 1403/11/03

Ethics committee reference number
IR.MUMS.REC.1403.381

Health conditions studied

1

Description of health condition studied
Lewy body dementia

ICD-10 code
G31.83

ICD-10 code description
Dementia with Lewy bodies

Primary outcomes

1

Description
Cognitive impairment

Timepoint
Evaluation is done at the beginning of the study and at the twelfth week.

Method of measurement
Mini-Mental State Examination (MMSE) and Montreal Cognitive Assessment (MoCA) will be used for cognitive assessment.

Secondary outcomes

1

Description
Serum level of α-Synuclein

Timepoint
At baseline and after 12 weeks from intervention

Method of measurement
ELISA

Intervention groups

1

Description
Intervention group: Trehalose (Shanxxi Fruiterco Co. Ltd. China) will be administered orally at a dose of 20 grams per day for up to three months.
Category
Treatment - Drugs

2

Description
Control group: Placebo (sucrose) will be administered 20 grams orally per day for three months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurology Department, Ghaem Hospital
Full name of responsible person
Ali Shoeibi
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Sponsors / Funding sources

1

Sponsor
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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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No further information available.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available