

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Evaluation of the therapeutic effects of trehalose in patients with Alzheimer disease

Protocol summary

Study aim

The aim of this study was to determine the effectiveness of trehalose on reducing the symptoms in AD patients.

Design

This study has been designed as pilot randomized, triple-blind, placebo-controlled and parallel trial.

Settings and conduct

Patients will be selected from Ibn Sina Hospital and they randomized to receive trehalose or normal saline as a placebo for 12 weeks. Participants, care providers, investigators, and outcome assessors, will be kept unaware of the treatment administered.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with probable Alzheimer disease with Mini-Mental State Examination (MMSE) score range from 10 to 23 and Not having other cognitive disorders. Exclusion Criteria: MMSE score higher than 23 or lower than 10, The presence of other cognitive disorders which will be evaluated by clinical assessment and brain imaging, Vascular dementia and Lewy body dementia, Previous history of head trauma, Use of alcohol and other drugs that affect cognitive functioning.

Intervention groups

Twenty patients with Alzheimer randomly will be divided into an intervention and a control group. Trehalose will be administered intravenously (15 g/week) for 12 weeks in the intervention group and the control group will be received normal saline as a placebo.

Main outcome variables

Changes in cognition status, which will be assessed with Clinical Dementia Rating (CDR) and MMSE tests.

General information

Reason for update

Acronym

Mycose AdminiStration for Heallng Alzheimer NEuropathy (MASHIANE)

IRCT registration information

IRCT registration number: **IRCT20130829014521N15**

Registration date: **2020-03-01, 1398/12/11**

Registration timing: **prospective**

Last update: **2020-03-01, 1398/12/11**

Update count: **0**

Registration date

2020-03-01, 1398/12/11

Registrant information

Name

Amirhossein Sahebkar

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 51 1882 9260

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-20, 1399/03/31

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the therapeutic effects of trehalose in patients with Alzheimer disease

Public title

Trehalose and Alzheimer disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Mini-Mental State Examination (MMSE) score range from 10 to 23 Not having other cognitive disorders
Exclusion criteria:
MMSE score higher than 23 or lower than 10 The presence of other cognitive disorders which will be evaluated by clinical assessment and brain imaging Vascular dementia and Lewy body dementia Previous history of head trauma Use of alcohol and other drugs that affect cognitive functioning

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: 10

Randomization (investigator's opinion)
Randomized

Randomization description
This study has been designed as pilot randomized, triple-blind, placebo-controlled and parallel trial. Simple randomization for allocation and sealed envelope approach would be considered for concealed allocation.

Blinding (investigator's opinion)
Triple blinded

Blinding description
This study has been designed as triple-blind and persons including participants, care providers, investigators, and outcome assessors, keeping unaware of the treatment administered. Drug and placebo vials have similar packaging and labeling and all recorded data will be encoded in the questionnaires and software.

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

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street.

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Approval date

2019-05-21, 1398/02/31

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.333

Health conditions studied

1

Description of health condition studied

Alzheimer disease

ICD-10 code

G30. 9

ICD-10 code description

Dementia in Alzheimer's disease, atypical or mixed type

Primary outcomes

1

Description

Change in CDR-SB and MMSE scores

Timepoint

At the beginning and end of the intervention trial (Day 0 and week 12)

Method of measurement

Clinical Dementia Rating Scale-Sum of Boxes (CDR-SB) and Mini-Mental State Examination (MMSE) questionnaire

Secondary outcomes

1

Description

Alterations in Alzheimer disease-related microRNA levels

Timepoint

Baseline and week 12

Method of measurement

Real-time quantitative PCR

2

Description

Alteration in serum levels of phosphorylated tau protein

Timepoint

Baseline and week 12

Method of measurement

ELISA

3

Description

Alteration in serum levels of Aβ42

Timepoint

Baseline and week 12

Method of measurement

ELISA

Intervention groups

1

Description

Intervention group: Trehalose will be administrated intravenously (15 g/week) for 12 weeks in the intervention group.

Category

Treatment - Drugs

2

Description

Control group: Normal saline as a placebo will be administrated intravenously for 12 weeks in the control group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebnesina hospital

Full name of responsible person

Amirhossein Sahebkar

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Ebnesina hospital, Horr Ameli Blvd., Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad 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

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

Amirhossein Sahebkar

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmaceutical biotechnology

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Person responsible for scientific inquiries

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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

"There is no further information"

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

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Amirhossein Sahebkar

Position