Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Safety and Efficacy of Sodium Pentaborate Pentahydrate in Patients with Mild to Moderate Alzheimer’s Disease: A Randomised, Double-Blind, Placebo-Controlled Phase 2 Trial

Protocol summary

Study aim

Determining the Safety and Efficacy of Sodium Pentaborate Pentahydrate in Patients with Mild to Moderate Alzheimer’s Disease

Design

A randomised, double-blind, placebo-controlled phase 2 clinical trial with a sample size of 60 participants (30 per group), in which block randomization will be performed using the RAS software.

Settings and conduct

This double-blind clinical trial will be conducted at a clinic affiliated with Tabriz University of Medical Sciences. Both participants and study personnel, including researchers and those responsible for conducting the study, will remain unaware of treatment allocation until the end of the study. Participants will take a daily oral dose of sodium pentaborate pentahydrate or placebo after meals for 6 months, with study visits scheduled for screening, randomization (baseline), and follow-ups at 1, 2, 4, and 6 months.

Participants/Inclusion and exclusion criteria

Participants must be aged 55 to 85, diagnosed with mild to moderate Alzheimer's disease, with an MMSE score between 10 and 24, evidence of episodic memory impairment, and stable use of Alzheimer’s medications. Exclusion criteria include major neurological or psychiatric disorders, significant amyloid-related abnormalities on MRI, and recent use of experimental drugs.

Intervention groups

Participants will be randomly assigned to two groups: one group will receive a placebo along with donepezil and 1000 mg of sodium pentaborate pentahydrate, while the other group will receive a placebo along with donepezil.

Main outcome variables

Alzheimer’s Disease Assessment Scale – Cognitive Subscale (ADAS-Cog13)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220614055167N7**
Registration date: **2025-04-11, 1404/01/22**
Registration timing: **prospective**

Last update: **2025-04-11, 1404/01/22**
Update count: **0**

Registration date

2025-04-11, 1404/01/22

Registrant information

Name

Saeid Safiri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-30, 1404/02/10

Expected recruitment end date

2026-01-20, 1404/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Safety and Efficacy of Sodium Pentaborate Pentahydrate in Patients with Mild to Moderate Alzheimer’s Disease: A Randomised, Double-Blind, Placebo-Controlled Phase 2 Trial

Public title
Evaluating the Safety and Effectiveness of Sodium Pentaborate Pentahydrate for Mild to Moderate Alzheimer’s: A Phase 2 Clinical Trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 55 and 85 years Diagnosis of mild to moderate Alzheimer’s disease based on the National Institute on Aging and Alzheimer’s Association (NIA-AA) criteria Mini-Mental State Examination (MMSE) score between 10 and 24 Evidence of episodic memory impairment (≥1 standard deviation below age norm) Use of stable doses of Alzheimer’s medications

Exclusion criteria:
Presence of major neurological or psychiatric disorders Significant amyloid-related imaging abnormalities (ARIA) detected on magnetic resonance imaging (MRI) Recent use of experimental drugs

Age
From **55 years** old to **85 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly assigned to two groups: the first group will receive sodium pentaborate pentahydrate (at a dose of 1000 mg) in combination with donepezil, while the second group will receive donepezil alongside a placebo. To allocate participants to the groups, a balanced block randomisation method at the individual level will be employed. The randomisation sequence will be generated by an independent individual, who is not involved in the study procedures, using RAS (Random Allocation Software). In this process, blocks of four with different arrangements of groups A and B will be used, and allocation will be carried out based on a random number table. The randomisation process in RAS involves the following steps: Defining the intervention group (A) and control group (B) in the software; Setting the block size (blocks of four); Generating all possible allocation combinations within each block (e.g., AABB, ABAB, ABBA, etc.); Randomly selecting blocks using a random number table; Concatenating the selected blocks to create the final allocation sequence. After evaluating the inclusion and exclusion criteria, eligible participants will be enrolled in the study sequentially and assigned to group A or B according to the generated sequence. For example, if the sequence begins with A, B, B, A, the first four participants who meet the criteria and enter the study will be allocated in this order. The allocation process will be concealed, and none of the researchers involved in the study will be aware of the allocation sequence or have the ability to manipulate participant assignment. Only the person responsible for generating the randomisation sequence will have access to it. To ensure blinding, each medication package will be labelled with a unique 10-digit random code. These codes will prevent both the participants and the study investigators from knowing whether the administered treatment is the active drug or the placebo.

Blinding (investigator's opinion)
Double blinded

Blinding description
Both participants and study personnel, including investigators and those responsible for study execution, will remain blinded to treatment allocation until the study is completed. Each active sodium pentaborate pentahydrate treatment group will have a matching placebo group with identical tablets to maintain blinding. Participants will take their assigned medication as a once-daily oral tablet after meals for six months. Study visits are scheduled for screening and randomisation (baseline), as well as at months 1, 2, 4, and 6.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Tabriz University of Medical Sciences

Street address
Golgasht Street, Tabriz University of Medical Sciences

City
Tabriz

Province
East Azarbaijan

Postal code
5166616471

Approval date
2025-03-10, 1403/12/20

Ethics committee reference number
IR.TBZMED.REC.1403.1080

Health conditions studied

1

Description of health condition studied
Mild to Moderate Alzheimer’s Disease
ICD-10 code
G30
ICD-10 code description
Alzheimer's disease

Primary outcomes

1

Description
Changes in the Alzheimer’s Disease Assessment Scale – Cognitive Subscale (ADAS-Cog13)
Timepoint
At baseline (prior to the initiation of the intervention) and six months after the start of the intervention
Method of measurement
Cognitive Subscale (ADAS-Cog13)

Secondary outcomes

1

Description
Changes in the Clinical Dementia Rating – Sum of Boxes (CDR-SB)
Timepoint
At baseline (prior to the initiation of the intervention) and six months after the start of the intervention
Method of measurement
Clinical Dementia Rating – Sum of Boxes (CDR-SB)

2

Description
changes in the Alzheimer’s Disease Cooperative Study – Activities of Daily Living Scale (ADCS-ADL)
Timepoint
At baseline (prior to the initiation of the intervention) and six months after the start of the intervention
Method of measurement
Alzheimer’s Disease Cooperative Study – Activities of Daily Living Scale (ADCS-ADL)

Intervention groups

1

Description
The intervention group will receive 1000 mg of sodium pentaborate pentahydrate daily (administered as two 500 mg capsules, preferably after lunch and dinner) under the brand name CogniBor (manufactured by APharma), in combination with donepezil, for a duration of six months.
Category
Treatment - Drugs

2

Description
The control group will receive a placebo (administered as two 500 mg capsules, preferably after lunch and dinner) under the brand name CogniBor (manufactured by APharma), in combination with donepezil, for a duration of six months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz University of Medical Sciences
Full name of responsible person
Saeid Safiri
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Sponsors / Funding sources

1

Sponsor
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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

Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Saeid Safiri

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Epidemiology

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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