Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Intrathecal injection of mesenchymal stem cells (MSC) and repetitive pulsed magnetic stimulation (rTMS) in patients with Alzheimer's disease: a phase I clinical trial

Protocol summary

Study aim
Evaluation of the safety and feasibility of mesenchymal stem cell administration in combination with repetitive transcranial magnetic stimulation for people with Alzheimer's disease

Design
Clinical trial without control group, phase 1 on 15 patients in one group as before and after study

Settings and conduct
At Besat Hospital, patients with Alzheimer's disease will receive intrathecal mesenchymal stem cell injections and a series of repetitive transcranial magnetic stimulation sessions targeting specific brain regions associated with cognitive function. Patients will be enrolled in the study as a single group and compared to before the intervention. Therefore, blinding is not possible in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Age 50–85 years 2. Meet criteria for probable Alzheimer's disease (AD) according to the National Institute on Aging-Alzheimer's Association (NIA-AA) 3. a score of 18–26 on the Mini-Mental Examination (MMSE) 4. confirmed neurodegeneration due to atrophy on structural brain MRI. Exclusion criteria: (1) neurodegenerative diseases other than AD (2) severe FLAIR white matter enhancement on MRI at baseline, defined as a cap or band (periventricular white matter enhancement) ≥ 10 mm and deep white matter lesions ≥ 25 mm (based on the modified Fazekas ischemia criteria); (3) major psychiatric disorders; (4) History of stroke within 3 months of study entry; (5) Active hepatic, renal, hematological, or pulmonary disorders. (6) history of malignancy; (7) Intrathecal injection is difficult or contraindicated.

Intervention groups
Alzheimer's disease patients referred to Be'sat Hospital will undergo intrathecal injection of mesenchymal stem cell and 40 sessions of repetitive transcranial magnetic stimulation (over 8 weeks) .

Main outcome variables
Montreal Cognitive Assessment Score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250310065011N1**
Registration date: **2025-04-17, 1404/01/28**
Registration timing: **prospective**

Last update: **2025-04-17, 1404/01/28**
Update count: **0**

Registration date
2025-04-17, 1404/01/28

Registrant information

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Kamyab Alizadeh

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
2026-05-22, 1405/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Intrathecal injection of mesenchymal stem cells (MSC) and repetitive pulsed magnetic stimulation (rTMS) in patients with Alzheimer's disease: a phase I clinical trial

Public title

Treatment of Alzheimer's disease with mesenchymal stem cells and repetitive pulsed magnetic stimulation (rTMS)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 50 to 85 years Meets criteria for probable Alzheimer's disease dementia according to the National Institute on Aging-Alzheimer's Association (NIA-AA) Working Group Scored 18-26 on the Mini-Mental State Examination (MMSE) screening Eligible patients will then be screened with MRI imaging and will be enrolled in the study once neurodegeneration due to atrophy is confirmed on structural brain MRI

Exclusion criteria:

(1) have neurodegenerative diseases other than Alzheimer's disease have severe FLAIR white matter enhancement on MRI at baseline, defined as a cap or band (periventricular white matter enhancement) ≥ 10 mm and deep white matter lesions ≥ 25 mm (based on the modified Fazekas ischemia criteria); have major psychiatric disorders; History of stroke within 3 months of study entry; Active hepatic, renal, hematological, or pulmonary disorders. Current or prior history of malignancy; Intrathecal injection is difficult or contraindicated for the patient.

Age

From **50 years** old to **85 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of AJA University of Medical Sciences

Street address

Etemadzadeh st, Fatemi gharbi st, Tehran

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1411718541

Approval date

2025-03-01, 1403/12/11

Ethics committee reference number

IR.AJAUMS.REC.1403.292

Health conditions studied

1

Description of health condition studied

Alzheimer's disease

ICD-10 code

G30

ICD-10 code description

Alzheimer's disease

Primary outcomes

1

Description

Montreal Cognitive Assessment Score

Timepoint

At the beginning of the study (before the intervention) and after the last repetitive pulsed magnetic stimulation session

Method of measurement

The MOCA (Montreal Cognitive Assessment) is a psychological tool designed to assess cognitive functions in adults and consists of 30 questions that take approximately 10 to 15 minutes to complete. The test is divided into several sections: attention and concentration (number repetition and naming), short-term memory (word recall), language (describing objects), visual and spatial abilities (copying geometric shapes), as well as executive function and long-term memory. The total score for the test can range from 0 to 30, with a score above 26 considered normal functioning, 18 to 25 indicating mild cognitive impairment, and below 18 indicating moderate or severe cognitive impairment.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Alzheimer's patients will receive intrathecal mesenchymal stem cells injections (1 × 10^6 cells per kilogram) (Prepared in one of the specialized stem cell centers in Iran) and then a series of repetitive pulsed magnetic stimulation (40 sessions, 5 days per week, 20 Hertz , 30 pulses per train) (Using devices available in the Iranian market) targeting specific brain regions associated with cognitive function.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Yousef Karimi's private clinic
Full name of responsible person
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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
Artesh 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
Artesh University of Medical Sciences
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Dr. Yousef Karimi
Position
Non-academic specialist physician
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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
Not applicable

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
All data is potentially shareable after de-identifying individuals

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
Researchers working in academic and scientific institutions as well as people working in the industry can apply to receive data.

Under which criteria data/document could be used
The data can be used for research purposes.

From where data/document is obtainable
Dr. Reza Eslami should be contacted.
Email:rezaeslami7@yahoo.com

What processes are involved for a request to access data/document
After contact, information is sent within a few days.

Comments