Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluating the effect of deep brain stimulation (DBS) on neuropsychiatric tests parameters deviation and hippocampal volumetry in patients with Alzheimer's disease (AD)

Protocol summary

Study aim
Determining the effect of deep brain stimulation (DBS) in reducing the intensity of psychological changes, reducing drug treatment costs and improving life satisfaction of Alzheimer's patients.

Design
Uncontrolled clinical trial; phase 1 carried on 4 patients; and followed at 0,6 and 12 month period after the surgery

Settings and conduct
Surgery and data collection will be run at Imam Khomeini Hospital Center in Tehran. After being implanted in the patient's brain during the first days, the device will be turned off by the generator implanted under the patient's clavicle and will be turned on within two weeks, and the patient will visit the hospital clinic during follow up.

Participants/Inclusion and exclusion criteria
The study involved patients aged 45 to 80 years with functional cognitional decline and a stable cholinesterase inhibitor dose. Eligible participants had a CDR global rating of 0.5 or 1.0 and an ADAS cog 11 score of 12 to 24. Exclusion criteria included brain tumors, mental retardation, claustrophobia, metal implants, insulin-dependent diabetes, cardiovascular or neurovascular disorders, unwillingness to comply, and life expectancy less than 1 year.

Intervention groups
The intervention group includes Alzheimer's patients according to the mentioned protocol, during a brain surgery, the electrodes of the DBS device used will ve placed in the anterior fornix of the patients.

Main outcome variables
Determining and comparing the changes in MMSE and ADAS cog psychological test scores, the changes in the hippocampus volume of patients and the level of beta amyloid in the cerebrospinal fluid of patients before and after deep brain stimulation of Alzheimer's patients.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240903062942N1**
Registration date: **2024-09-27, 1403/07/06**
Registration timing: **registered_while_recruiting**

Last update: **2024-09-27, 1403/07/06**
Update count: **0**

Registration date
2024-09-27, 1403/07/06

Registrant information

Name
Ramtin Pourahmad

Name of organization / entity

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Iran (Islamic Republic of)

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+98 21 4489 7836

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-09-22, 1403/07/01

Expected recruitment end date
2024-10-06, 1403/07/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effect of deep brain stimulation (DBS) on neuropsychiatric tests parameters deviation and hippocampal volumetry in patients with Alzheimer's disease (AD)

Public title
Effect of deep brain stimulation in treatment of Alzheimer's disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with possible Alzheimer's criteria according to the National Alzheimer's Institute and CDR global scales and ADAS Cog 11
Exclusion criteria:
Age
From **45 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **4**
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
Ethics committee of Tehran University of Medical Sciences
Street address
No. 1, Nastaran deadend, Ensafi alley, Amir Ebrahim Ave., Bagh Feiz, Tehran
City
Tehran
Province
Tehran
Postal code
1473164143
Approval date
2024-08-31, 1403/06/10
Ethics committee reference number
IR.TUMS.IKHC.REC.1403.235

Health conditions studied

1

Description of health condition studied
Alzheimer's disease
ICD-10 code
G30.9
ICD-10 code description
Alzheimer's disease, unspecified

Primary outcomes

1

Description
Neuropsychological cognition disorder
Timepoint
Measurement of cognitional disorders at First (before surgery), 6 and 12 month after procedure
Method of measurement
MMSE clinical test

2

Description
Neuropsychological cognition disorder
Timepoint
At first (before procedure), 6 and 12 month after procedure
Method of measurement
ADAS-cog clinical test

3

Description
Hippocampal volumetry
Timepoint
At first (before procedure), 6 and 12 month after procedure
Method of measurement
MRI

4

Description
CSF Beta Amyloid
Timepoint
At first (before procedure), 6 and 12 month after procedure
Method of measurement
ELISA test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Deep Brain Stimulation
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khimeini Hospital Complex
Full name of responsible person
Abbas Tafakhori
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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No23, Valiasr ave, Dameshgh st, Vice chancellor for research, Tehran University of Medical Sciences
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Gojelou@farabi.tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
10
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
Tehran University of Medical Sciences
Full name of responsible person
Ramtin Pourahmad
Position
Medical student
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Other areas of specialty/work
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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
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All patient's information included in the trial will be shared after making the personal data undetectable for each participant
When the data will become available and for how long
Data access phase will be started right after the publication
To whom data/document is available
Researchers working in universities research labs or related scientific organizations
Under which criteria data/document could be used
Just for investigatin the accuracy of published content and also as an answer for inquiries raised from published article
From where data/document is obtainable
Ramtin Pourahmad; Tel: 09144857404; E-mail: Ramtinpourahmad79@gmail.com Dr. Abbas Tafakhori; E-mail: a_tafakhori@sina.tums.ac.ir
What processes are involved for a request to access data/document
After requesting for data access the requested documents will be shared after inspecting the access competemcy.
Comments