Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Evaluating the effect of Pregabalin in treatment of Behavioral and psychological symptoms of dementia(BPSD)

Protocol summary

Study aim
Comparing and determining the Efficacy of Pregabalin vs Placebo in Psychological and Behavioral Symptoms of Dementia in Patients with Alzheimer's or mixed Vascular Dementia Comparing and determining the Effect of Pregabalin vs Placebo in Increasing Dementia Patient's quality of life

Design
This is a double-blinded parallel clinical trial, with two groups consisting of a drug or main group and a placebo or control group. Two-digit randomizing table was used.

Settings and conduct
This clinical trial takes place in Roozbeh hospital, and is supervised by a clinical pharmacist, a neurologist and a pharmacy student. Blinding is done by a clinical pharmacist and no one from the research team is aware of the group The drugs are given to patients in the Clinique by the neurologist or the investigator and the patients are not aware of their groups. NPI, Behave-AD and dementia quality of life questionnaire is filled by one of the supervisors.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients diagnosed with Alzheimer's or mixed vascular Dementia based on DSM V criteria and the severity of their disease in moderate to severe based on their FAST test result (Scores: 5-6) Exclusion Criteria: Patients with history of major psychological disorders currently under treatment History of Epilepsy and other neurologic disorders such as multiple sclerosis or major head trauma

Intervention groups
Prescribing Pregabalin the drug group, initial dose: 50 mg HS and increasing every week until 150 mg BD for 3 months, Prescribing placebo the control group with the exact same manner for 3 months

Main outcome variables
Scores of the dementia-quality of life, NPI and Behave-AD questionnaires

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201201049553N1**
Registration date: **2021-07-08, 1400/04/17**
Registration timing: **prospective**

Last update: **2021-07-08, 1400/04/17**
Update count: **0**

Registration date
2021-07-08, 1400/04/17

Registrant information

Name
Leyla Maleki

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
2021-07-23, 1400/05/01

Expected recruitment end date
2022-07-23, 1401/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluating the effect of Pregabalin in treatment of Behavioral and psychological symptoms of dementia(BPSD)

Public title
Effect of Pregabalin in Behavioral and psychological symptoms of dementia(BPSD)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with dementia of the following types: Alzheimer's, vascular dementia or mixed vascular dementia, based on DSM V criteria Patients with moderate to severe dementia based on the result of diagnostic tools such as FAST or MoCA
Exclusion criteria:
Other types of dementia such as Lewy body or frontotemporal dementia History of major psychological disorders History of drug abuse History of epilepsy or other neurological disorders such as Multiple Sclerosis or head concussion which may exacerbate behavioral symptoms
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **58**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling takes place when a patient is referred to the neurology clinic of Roozbeh Hospital, and the patient meets the study's inclusion and exclusion criteria. For sampling allocation, permuted block randomization technique is used to prepare a randomizing table. Regarding the fact that patients divide in two groups with 1:1 allocation ratio (29 patients in control group and 29 patients in treatment group), the block size is 4, the patients will be divided into blocks of 4 and will receive medication or placebo (A or B), for assigning blocks we use random number generation. A random number will be generated for each treatment assignment and the permutation will be determined based on the numbers assigned from the greatest to the smallest number. To avoid having a block size of 2, we will have 13 blocks with the size 4 and a block of size 6.
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinding is carried out by a clinical pharmacist with a randomizing table. The medications are given to the investigator with a specified code. Neither the consulting physician nor the investigator have any any information on the coding process. Placebos are 100 percent identical both in appearance and in number to the medication itself.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee The institute of pharmaceutical sciences- Tehran University Of medical Sciences-TIP
Street address
Faculty of pharmacy, Tehran University of medical sciences, Poursina Av. Keshavaraz blvd, Tehran, Iran
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Tehran
Province
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Postal code
14176-13151
Approval date
2021-01-19, 1399/10/30
Ethics committee reference number
IR.TUMS.TIPS.REC.1399.160

Health conditions studied

1

Description of health condition studied
Behavioral and psychological symptoms of dementia (BPSD)
ICD-10 code
F03.91
ICD-10 code description
Unspecified dementia with behavioral disturbance

Primary outcomes

1

Description
Sum of score for Behavioural Pathology in Alzheimer's Disease questionnaire
Timepoint
Before Taking pregabalin, and 4,8,12 weeks after taking pregabalin
Method of measurement
Behavioural Pathology in Alzheimer's Disease questionnaire

2

Description
sum of score for Neuropsychiatric Inventory questionnaire
Timepoint
Before Taking pregabalin, and 4,8,12 weeks after taking pregabalin
Method of measurement
Neuropsychiatric Inventory (NPI) questionnaire

Secondary outcomes

1

Description
Sum of score of dementia quality of life questionnaire
Timepoint
Before taking Pregabalin and on the weeks of 4,8,12 after taking pregabalin
Method of measurement
dementia quality of life (qol) questionnaire

Intervention groups

1

Description
Intervention group: Patients in this group receive Pregabalin with the initial dose 50mg per day, the dose increases every week to the maximum of 150 mg twice a day for 12 weeks. Both Pregabalin Tablets and placebos are manufactured by Sobhan Darou Pharmaceutical company.
Category
Treatment - Drugs

2

Description
Control group: Patients in this group are given placebo once a day for the first week and then twice a day for 12 weeks. placebos are the exact physical replica of Levetiracetam tablets manufactured by Sobhan Darou Pharmaceutics. All the excipients are chemically the same and only the API (Active Pharmaceutical Ingredient) is removed
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Roozbeh Psychiatric Hospital
Full name of responsible person
Leyla Maleki
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Tehran University of Medical Sciences Deputy of Research and Technology
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
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Leyla maleki

Position
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Latest degree
Ph.D.

Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
No - There is not 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
changes in score of Behave-AD and NPI

When the data will become available and for how long
starting 3 months after publication

To whom data/document is available
Available to clinical and industrial pharmacists and Neurologists

Under which criteria data/document could be used
Please contact us beforehand.

From where data/document is obtainable
Please contact Leyla Maleki via Leylaamaleki@gmail.com

What processes are involved for a request to access data/document
Please contact us beforehand

Comments