

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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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 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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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 Pharmaceuticals. 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

Tehran University of Medical Sciences Deputy of Research and Technology

Full name of responsible person

Mohammad Ali Sahraian

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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

Tehran University of Medical Sciences

Full name of responsible person

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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