

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2269 2781

##### Email address

l-maleki@student.tums.ac.ir

##### 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

###### **City**

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 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

#### **Street address**

Roozbeh Hospital, Lashkar Crossroad, South Karegar Street, District 11, Tehran

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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

#### **Street address**

6th floor, Central building of Tehran University Of medical Scinces, Qods st., Keshavarz Blvd., Tehran

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#### **Web page address**

<https://vcr.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 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**

Leyla maleki  
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student  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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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