

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparing the Effectiveness of Memantine and Donepezil on the Cognitive Status of the elderly with vascular dementia

Protocol summary

Study aim

Determining and comparing the Effectiveness of memantine and donepezil on the cognitive status of the elderly with vascular dementia

Design

A clinical trial without a control group, with parallel groups, single blind, randomized, phase 3 on 60 patients. The rand function of Excel software was used for randomization.

Settings and conduct

The elderly referring to Amirkola Geriatric Clinic are screened with the MMSE test, and those with a score of less than 24 are introduced to the second colleague to receive medication after performing preliminary tests and ruling out reversible causes of dementia. divides the patients into two groups. In the memantine group, patients are treated with memantine tablets 5 mg twice a day for one to two weeks, then 24 mg twice a day for up to 6 months. Patients in the donepezil group are treated with Donepezil 5 tablets daily for 4 to 6 weeks, then 10 mg daily for up to 6 months. Patients are re-tested with MMSE and Eden Brook tests in the third and sixth month after the start of treatment. In this study, only the first colleague He is not aware of the results and type of medicine of each patient..

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age more than 65 years MMSE score less than 24 with evidence of metabolic disease or evidence in favor of vascular dementia on MRI Exclusion criteria: Patients with psychotic disorders Intellectual disability Patients who are already being treated for cognitive impairment Confirmed history of bipolar disorder and major depression Alzheimer's disease and other neurological diseases

Intervention groups

One group received memantine and the other group received donepezil

Main outcome variables

Variables such as cognitive status, memory, attention

and orientation, speech fluency, language and drug side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190525043700N6**

Registration date: **2024-05-29, 1403/03/09**

Registration timing: **prospective**

Last update: **2024-05-29, 1403/03/09**

Update count: **0**

Registration date

2024-05-29, 1403/03/09

Registrant information

Name

Romina Hamzhepour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-21, 1403/04/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effectiveness of Memantine and Donepezil on the Cognitive Status of the elderly with vascular dementia

Public title

Comparing the Effectiveness of Memantine and Donepezil on elderly with dementia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age > 65 y MMSE Score < 24 + Evidence of metabolic disease Evidence in favor of vascular dementia in MRI

Exclusion criteria:

Patients with psychotic disorders Intellectual disability Patients who are already being treated for cognitive disorders Confirmed history of bipolar disorder or depression Patients with Alzheimer's and other neurological diseases

Age

From **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of patients in both groups of 30 memantine and donepezil is done by random block allocation method and free website www.randomization.com or <http://randomizer.org> is used to generate the allocation sequence. The obtained sequence is written on separate sheets and placed in sealed envelopes and given to the second colleague to conduct the study...

Blinding (investigator's opinion)

Single blinded

Blinding description

The first colleague (student) is unaware of the random allocation list and which group each patient is in, and will be informed of the results at the end of the study...

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Health Research Institute - Babol University of Medical Sciences

Street address

Babol, Murad Bey, University Square, Nurse St

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Postal code

47176-47745

Approval date

2024-03-16, 1402/12/26

Ethics committee reference number

IR.MUBABOL.HRI.REC.1402.199

Health conditions studied

1

Description of health condition studied

Vascular dementia

ICD-10 code

F01.5

ICD-10 code description

Vascular dementia

Primary outcomes

1

Description

Investigating the cognitive status by comparing the MMSE and Edenbrook test results at the beginning, during the treatment and at the end of the treatment...

Timepoint

At the beginning of work, 3 months and 6 months after the start of treatment

Method of measurement

Through the Eden Brook test

Secondary outcomes

empty

Intervention groups

1

Description

Patients in the memantine group are treated with memantine tablets 5 mg twice a day for one to two weeks, then 10 mg twice a day for up to 6 months. (From Actover pharmaceutical company)...

Category

Treatment - Drugs

2

Description

Patients in the donepezil group are treated with 5 mg donepezil tablets daily for four to six weeks, then 10 mg daily for up to 6 months..

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic for the elderly in Amirkola city

Full name of responsible person

Dr. Romina hamzhepour

Street address

Naqvi Boulevard, Imam Ali Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

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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

Babol University of Medical Sciences

Proportion provided by this source

90

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

Babol University of Medical Sciences

Full name of responsible person

Dr.Romina hamzhepour

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Full name of responsible person

Dr.Maryam vajdi

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Latest degree

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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

Maintain confidentiality

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available