Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Nov 2026

Evaluation of the effectiveness of piracetam consumption in improving cognitive disorders in older adults with major depression disorder: A double-blind, placebo-controlled clinical trial

Protocol summary

Study aim

Evaluation of the efficacy of piracetam in improving cognitive impairment in elderly patients with major depressive disorder.

Design

The study is a double-blind, randomized clinical trial with parallel groups. Participants will be randomized 1:1 into intervention and control groups using Excel's RAND function. The sample size will be 90 eligible patients (45 per group), aged 60-80, from Khorshid Hospital in Isfahan.

Settings and conduct

The present study is a double-blind, randomized trial conducted on 90 eligible patients. Patients are randomly assigned to two groups: one receiving piracetam (800 mg daily) and the other receiving a placebo. The assessor (principal investigator), patients, and treating physician are blinded to group assignment. Cognitive function is compared using the NUCOG test before and after the 3-month study period.

Participants/Inclusion and exclusion criteria

Inclusion: Age 60-80, MDD per DSM-5, NUCOG <80, stable antidepressants ≥8 weeks. Exclusion: Severe liver/kidney disease, cognitive-affecting drugs/supplements, withdrawal consent, life-threatening events.

Intervention groups

Intervention Group: Patients receive standard antidepressants plus an 800 mg piracetam tablet three times daily. Control Group: Patients receive placebo capsules (800 mg Avicel), identical in appearance to the active drug, for three months.

Main outcome variables

Primary Outcomes: - Mean total NUCOG score before and after the study, within and between the piracetam and placebo groups. Secondary Outcomes: - The trend of NUCOG score changes over time and between groups. - Frequency of adverse events in the piracetam group.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250929067414N3**
Registration date: **2026-02-11, 1404/11/22**
Registration timing: **registered_while_recruiting**

Last update: **2026-02-11, 1404/11/22**
Update count: **0**

Registration date

2026-02-11, 1404/11/22

Registrant information

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Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-02-03, 1404/11/14

Expected recruitment end date

2028-02-03, 1406/11/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of piracetam consumption in improving cognitive disorders in older adults with major depression disorder: A double-blind, placebo-controlled clinical trial

Public title
piracetam consumption in improving cognitive disorders
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Elderly people aged 60 – 80 years Diagnosis of Major Depressive Disorder (MDD) Based on DSM-5 Criteria Confirmed cognitive impairment with a baseline NUCOG score below 80. Stable antidepressant regimen for at least eight weeks prior to study entry.
Exclusion criteria:
Occurrence of severe hepatic or renal disorders. Use of any medication or herbal supplement affecting cognitive function during the study. Unwillingness to continue the trial, at any time and for any reason during the study. Occurrence of specific, life-threatening adverse events such as unexplained bruising, gum bleeding, or sudden headache.
Age
From **60 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization process is carried out as follows: After confirming the eligibility criteria and obtaining informed consent, patients are allocated to the intervention and control groups using block randomization with a block size of 4 and with the help of the online software www.sealedenvelope.com. This process is performed by an independent colleague not part of the research team, and the results are placed in sequentially numbered, opaque, sealed envelopes. The principal investigator and the patients will be blinded to the allocation type (double-blind study).
Blinding (investigator's opinion)
Double blinded
Blinding description
To implement double-blinding, the Piracetam and placebo capsules will be identical in appearance and indistinguishable. These capsules will be packaged in opaque, coded boxes (labeled as Code A and Code B). This ensures that neither the participants nor the outcome assessment personnel will be aware of the actual content of the capsules (intervention or control). This process prevents potential bias in participant reports and clinical evaluations.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشکده داروسازی و تغذیه
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Approval date
2026-01-28, 1404/11/08
Ethics committee reference number
IR.MUI.PHANUT.REC.1404.186

Health conditions studied

1

Description of health condition studied
Cognitive impairments associated with major depression in the elderly
ICD-10 code
F32.2
ICD-10 code description
Major depressive disorder, single episode, severe without psychotic features

Primary outcomes

1

Description
Comparison of the mean total NUCOG score in patients with Major Depressive Disorder, both within each group and between the piracetam and placebo groups.
Timepoint
Before the intervention and at the end of the third month after the start of the intervention
Method of measurement
The Neuropsychiatry Unit Cognitive Assessment (NUCOG) test

Secondary outcomes

1

Description
Comparison of changes in mean scores across different cognitive domains of the NUCOG test over time within each group.
Timepoint
Before the intervention and at the end of the third month after the start of the intervention
Method of measurement
NUCOG test

2

Description
Determination and comparison of the frequency distribution of adverse effects in the piracetam-receiving and placebo groups.
Timepoint
During the intervention with at least monthly monitoring.
Method of measurement
Patient interview

Intervention groups

1

Description
Intervention group: Patients receive an 800 mg oral piracetam tablet (manufactured by Alborz Darou Company) three times daily for 3 months.
Category
Treatment - Drugs

2

Description
Control group: Patients receive a placebo capsule containing 800 mg of Avicel, which is completely similar in appearance to the piracetam tablet, three times daily for 3 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Khorshid Hospital, Isfahan.
Full name of responsible person
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Sponsors / Funding sources

1

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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
Esfahan University of Medical Sciences
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
Esfahan University of Medical Sciences
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Specialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
All data can potentially be shared after de-identifying of individuals.

When the data will become available and for how long
6 months after the publication of the results.

To whom data/document is available
Researchers employed in academic and scientific institutions.

Under which criteria data/document could be used
The use of documents with proper citation is permitted.

From where data/document is obtainable
Email to the corresponding author. Mahsa Panahishokouh mahsapanahishokooh@gmail.com

What processes are involved for a request to access data/document
Requests for data access must be submitted in writing to the principal investigator, specifying the intended purpose. If approved, coded data (without identifying information) will be provided after signing a confidentiality agreement.

Comments