Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

The Effect of Oral Magnesium Supplementation on Cognitive Impairment Induced by Electroconvulsive Therapy in ECT Recipients: A Randomized, Double-Blind, Placebo-Controlled Clinical Trial

Protocol summary

Study aim

Investigating the effect of oral magnesium supplementation on cognitive dysfunction induced by electroconvulsive therapy in ECT recipients

Design

A double-blind, randomized, parallel-group clinical trial. Patients are randomly assigned 1:1 to intervention or control groups using Excel's RAND function. The total sample size is 54 patients (27 per group). The study population includes patients aged 18-65 eligible for ECT based on psychiatrist diagnosis at Khorshid Hospital, Isfahan.

Settings and conduct

This double-blind RCT on 54 ECT patients compared daily 250 mg magnesium vs. placebo. The assessor, patients, and physician were blinded. MoCA scores were compared pre- and 24h post-ECT.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients aged 18-65 years, scheduled to receive ECT as confirmed by a psychiatrist. Exclusion Criteria:History of epilepsy, dementia, or structural brain injury; severe/uncontrolled cardiac, renal, or hepatic disease; pregnancy/lactation; active substance/alcohol abuse; concurrent benzodiazepine use; history of psychosis; recent (past month) use of magnesium or cognition-affecting drugs; allergy/intolerance to magnesium.

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 MoCA score before and after ECT, within and between the magnesium and placebo groups.Secondary Outcomes:- Trend of changes in MoCA scores over time and across different cognitive domains, within and between groups.- Frequency of adverse events in the magnesium group.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250929067414N2**
Registration date: **2025-12-27, 1404/10/06**
Registration timing: **prospective**

Last update: **2025-12-27, 1404/10/06**
Update count: **0**

Registration date

2025-12-27, 1404/10/06

Registrant information

Name

Mahsa panahishokouh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-12-31, 1404/10/10

Expected recruitment end date

2027-05-31, 1406/03/10

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Oral Magnesium Supplementation on Cognitive Impairment Induced by Electroconvulsive Therapy in ECT Recipients: A Randomized, Double-Blind, Placebo-Controlled Clinical Trial

Public title
Magnesium Supplementation on Cognitive Impairment Induced by Electroconvulsive
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Male and female patients aged between 18 and 65 years Receiving Electroconvulsive Therapy (ECT) as diagnosed and confirmed by the treating psychiatrist.
Exclusion criteria:
A history of diagnosable neurological disorders including epilepsy, dementia, or structural brain injuries. Severe or uncontrolled systemic diseases such as cardiac, renal, or hepatic failure. Pregnancy and breastfeeding Active substance or alcohol abuse. Concurrent use of benzodiazepines. History of psychosis. Consumption of magnesium supplements or medications affecting cognitive function within the past month. History of allergy or intolerance to magnesium or its products.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **54**
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 magnesium supplement 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
The Ethics Committee of the Faculty of Pharmacy and Nutrition
Street address
hezarjreeb street
City
Isfahan
Province
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Postal code
73461-81746
Approval date
2025-11-29, 1404/09/08
Ethics committee reference number
IR.MUI.PHANUT.REC.1404.144

Health conditions studied

1

Description of health condition studied
Cognitive Impairment Induced by Electroconvulsive Therapy
ICD-10 code
F32.9
ICD-10 code description
Major depressive disorder, single episode, unspecified

Primary outcomes

1

Description
Comparison of the mean total cognitive score (MoCA) before and after ECT, both within each group and between the magnesium 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 Montreal Cognitive Assessment test

Secondary outcomes

1

Description
Trend of changes in MoCA scores over time and across different cognitive domains, within and between groups.
Timepoint
Before the intervention and at the end of the third month after the start of the intervention.
Method of measurement
MoCA test

2

Description
Frequency of adverse events in the magnesium group.
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
Treatment - Drugs

Recruitment centers

1

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

1

Sponsor
Name of organization / entity
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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
Full name of responsible person
Mahsa panahishokouh
Position
Specialist
Latest degree
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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