

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of memantine on cognitive impairments after ECT in elderly with major depressive disorder: a randomized double-blind placebo-controlled clinical trial

Protocol summary

Study aim

The effect of memantine on cognitive impairments after Electroconvulsive Therapy in elderly patients with major depressive disorder

Design

The study will be a double-blind clinical trial. Prior to starting medication and ECT sessions, the patient's demographic and depression questionnaires (GDS) will be completed and the Addenbrooke's Cognitive Examination test will also be completed. Patients will be randomly assigned to memantine or placebo. 24 hours after the last ECT session, patients will be re-evaluated for Addenbrooke's Cognitive Examination (ACE) test and GDS and medication side effect checklist and the results of the tests will be analyzed. Random allocation will be used in this trial based on balance block randomization and by 4:1 blocks. To concealment, table of block will be used by one of researchers, other than interviewer and who assess patients in follow-up visits, to write number of each participants on box of additional drugs. Therefore, all of patients, interviewer and who assess patients in follow-up visits will be unaware if each number belongs to which group.

Settings and conduct

Hospital

Participants/Inclusion and exclusion criteria

Diagnosis of MDD Clinical Indication for ECT Lack of diagnosis of dementia or delirium Lack of Hx of Major Axis I disorder (Schizophrenia, Schizoaffective, Bipolar I, II) Lack of Medical contraindication for ECT

Intervention groups

The intervention group will receive 10 mg memantine in addition to electroconvulsive therapy from 24 hours before the start of the first session treatment to 24 hours after the last session and the control group receive placebo.

Main outcome variables

Cognition score according to Addenbrooke's Cognitive Examination Depression score according to Geriatric Depression Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151122025191N2**

Registration date: **2020-09-17, 1399/06/27**

Registration timing: **prospective**

Last update: **2020-09-17, 1399/06/27**

Update count: **0**

Registration date

2020-09-17, 1399/06/27

Registrant information

Name

Behnam Shariati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6435 2331

Email address

shariati.b@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of memantine on cognitive impairments after ECT in elderly with major depressive disorder: a randomized double-blind placebo-controlled clinical trial

Public title

The effect of memantine on post-ECT cognition in depressed elderly

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of Major Depressive Disorder Clinical Indication for Electroconvulsive Therapy

Exclusion criteria:

Diagnosis of Dementia
Diagnosis of Delirium
Hx of Major Axis I disorder (Schizophrenia, Schizoaffective, Bipolar I, II)
Medical contraindication

Age

From **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be used in this trial based on balance block randomization and by 4:1 blocks. To do study with concealment, table of block will be used by one of researchers, other than interviewer and who assess patients in follow-up visits, to write number of each participants on box of additional drugs. Therefore, all of patients, interviewer and who assess patients in follow-up visits will be unaware if each number belongs to which group

Blinding (investigator's opinion)

Double blinded

Blinding description

To do study with concealment, table of block will be used by one of researchers, other than interviewer and who assess patients in follow-up visits, to write number of each participants on box of additional drugs. Therefore, all of patients, interviewer and who evaluates patients in follow-up visits will be unaware if each number belongs to which groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

ethics committee of Iran University of Medical Sciences

Street address

No. 28, 28th street, Arashmehr Ave., Jalal e Al e Ahmad Highway.,

City

Tehran

Province

Tehran

Postal code

1445713363

Approval date

2020-09-02, 1399/06/12

Ethics committee reference number

IR.IUMS.FMD.REC.1399.376

Health conditions studied**1****Description of health condition studied**

Major Depressive Disorder

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes**1****Description**

Addenbrooke's Cognitive Examination Score

Timepoint

before and 24 hour after electroconvulsive treatment

Method of measurement

Addenbrooke's Cognitive Examination-II Score

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: From the day before the ECT sessions, the patient will receive 10mg/day Memantine

tablet, which will continue until the last ECT session. Each patient will take between 6 and 8 sessions of ECT. According to the ECT protocol, the shock starts bilaterally (bitemporal) with a power of 35% and the minimum seizure required is 25 seconds. If this time is not reached, according to the anesthesiologist's opinion in the same session shock will be repeated. The interval between ECT sessions is every other day, and the energy will be increased in each session from 10 to 15% based on the seizure timer of the previous session to eventually reach 100% of the energy.

Category

Treatment - Drugs

2

Description

Control group: From the day before the ECT sessions, the patient will receive placebo, which will continue until the last ECT session. Each patient will take between 6 and 8 sessions of ECT. According to the ECT protocol, the shock starts bilaterally (bitemporal) with a power of 35% and the minimum seizure required is 25 seconds. If this time is not reached, according to the anesthesiologist's opinion in the same session shock will be repeated. The interval between ECT sessions is every other day, and the energy will be increased in each session from 10 to 15% based on the seizure timer of the previous session to eventually reach 100% of the energy.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrate Rasoule Akram Hospital

Full name of responsible person

Behnam Shariati

Street address

Hazrate Rasoole Akram Hospital., Niayesh St.,
Satarkhan Av., Tehran., IRAN

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behnamshariatimd@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Abbas Motevalian

Street address

Iran University of Medical Sciences., Shahid Hemmat
Highway., Tehran., Iran

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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

Iran University of Medical Sciences

Proportion provided by this source

50

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

Iran University of Medical Sciences

Full name of responsible person

Behnam Shariati

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

School of Behavioral Sciences and Mental Health.,
Shahid Mansouri Street., Niyayesh Street., Satarkhan
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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after being unidentified

When the data will become available and for how long

Access will be allowed 3 month after publication

To whom data/document is available

Researchers

Under which criteria data/document could be used

For use in meta-analysis studies with a written request stating the reason for the request and documentation

From where data/document is obtainable

Dr Behnam Shariati

What processes are involved for a request to access data/document

By Sending an email to the corresponding person along with mentioning the documents and the reason for the request.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Behnam Shariati

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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