Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness of rivastigmine and memantine in improving cognitive problems due to electroconvulsive therapy

Protocol summary

Study aim
Comparison of the effectiveness of rivastigmine and memantine in improving cognitive problems due to electroconvulsive therapy

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 45 patients

Settings and conduct
Patients admitted to the psychosomatic and psychiatric wards of Taleghani Hospital and the psychiatric ward of Emam Hossein Hospital are included in the study if they meet the inclusion criteria and are randomly divided into 3 groups receiving rivastigmine, memantine and placebo. Cognitive function of patients is assessed using the Montreal Cognitive Test one day before the start of ECT, two and six weeks after the start of treatment. The patient, the person performing the memory tests, the person delivering the drug to the patient, and the person analyzing the results will not be aware of the type of drug delivered to the patient.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 18-60, cooperation ability with our study, informed consent Exclusion criteria: history of neurocognitive disorder such as delirium and dementia, history of cardiac conductive disorder and arrhythmia, history of hepatic, renal, thyroid, and seizure disorders, history of sensitivity to rivastigmine and memantine, history of ECT within the the past 6 months, taking calcium channel blockers and cox-inhibitors.

Intervention groups
Intervention group 1: Rivastigmine starts with a dose of 1.5 mg in 24 hours and increases to 3 mg in 24 hours after a week. Intervention group 2: Memantine starts with a dose of 5 mg in 24 hours and increases to 10 mg in 24 hours after a week. Control group: Placebo starts with a dose of one capsule in 24 hours and increases to 2 capsules in 24 hours after a week. The duration of drug use in 3 groups will be 2 weeks.

Main outcome variables
Montreal Cognitive Scale score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190119042417N2**
Registration date: **2022-06-01, 1401/03/11**
Registration timing: **prospective**

Last update: **2022-06-01, 1401/03/11**
Update count: **0**

Registration date
2022-06-01, 1401/03/11

Registrant information

Name
Alireza Shamsi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2303 1357

Email address
ar.shamsi@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-05, 1401/03/15

Expected recruitment end date
2022-12-06, 1401/09/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the effectiveness of rivastigmine and memantine in improving cognitive problems due to electroconvulsive therapy

Public title
Evaluation the effectiveness of rivastigmine and memantine in improving cognitive problems due to electroconvulsive therapy

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Being in the age range of 18-60 years. Being a candidate to receive electroconvulsive therapy. Collaborate to perform Montreal cognitive assessment. Having informed consent to participate in the study.

Exclusion criteria:
History of neurocognitive disorders such as delirium and dementia History of cardiac conductive disorder and arrhythmia History of hepatic, renal, thyroid, and seizure disorders History of sensitivity to rivastigmine and memantine History of electroconvulsive therapy within the the past 6 months Taking calcium channel blockers and cox-inhibitors

Age
From **18 years** old to **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: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, we will use the restricted randomization method of block randomization. The size of all the blocks is the same and in this 3-group trial, we will have blocks of 9 people (including 3 people receiving memantine, 3 people receiving rivastigmine, and 3 people receiving placebo). Random allocation software is used to generate random sequences. Sequentially numbered, sealed opaque envelopes will be used to conceal allocation concealment. The random sequence created is registered on a card and the cards are placed in the letter envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. For the participants, based on the order of entry into the study, one of the envelopes is opened and the assigned group of the participant is determined.

Blinding (investigator's opinion)
Double blinded

Blinding description
Study participants, the person performing the memory tests (psychiatry resident) and the person delivering the drug to the patient (ward nurse) will not be aware of the type of drug delivered to the patient (memantine, rivastigmine or placebo). The person performing the tests will be same person (psychiatry resident) and the drugs will be prepared in the form of capsules with the help of the laboratory of the Faculty of Pharmacy of Shahid Beheshti University of Medical Sciences and in numbered boxes (drug No. 1, drug No. 2 and drug No. 3) will be delivered to the researcher and the researcher will be unaware of the type of drug until the data analysis is completed.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address
Daneshjo squire, Arabi street

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Tehran

Province
Tehran

Postal code
1985717443

Approval date
2021-03-02, 1399/12/12

Ethics committee reference number
IR.SBMU.MSP.REC.1399.691

Health conditions studied

1

Description of health condition studied
Psychiatric disorders with electroconvulsive therapy (ECT) indication

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Cognitive impairment

Timepoint

One day before starting ECT, 2 and 6 weeks after starting ECT

Method of measurement

Montreal Cognitive Scale (MOCA)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The day before receiving ECT and after the Montreal cognitive test, rivastigmine is started at a dose of 1.5 mg in 24 hours and increases to 3 mg (2 capsules) in 24 hours after one week. The drug will be taken once a day after lunch and will continue for 2 weeks. The rivastigmine used is rivastigmine 1.5 mg made by Razak Company, which has the same appearance as the drugs of memantine and placebo (prepared with the help of the Faculty of Pharmacy of Shahid Beheshti University of Medical Sciences). It will be delivered to the researcher in the form of capsules in numbered boxes.

Category

Treatment - Drugs

2

Description

Intervention group 2: The day before receiving ECT and after the Montreal cognitive test, memantine is started at a dose of 5 mg in 24 hours and increases to 10 mg (2 capsules) in 24 hours after one week. The drug will be taken once a day after lunch and will continue for 2 weeks. The memantine used is memantine 5 mg made by Sobhan Company, which has the same appearance as the drugs of rivastigmine and placebo (prepared with the help of the Faculty of Pharmacy of Shahid Beheshti University of Medical Sciences). It will be delivered to the researcher in the form of capsules in numbered boxes.

Category

Treatment - Drugs

3

Description

Control group: The day before receiving the electroshock and after the Montreal Cognitive Test, placebo starts with a dose of one capsule in 24 hours and increases to 2 capsules in 24 hours after a week. The placebo will be taken once a day, after lunch, and will last for 2 weeks. The placebo used in the same appearance as the drugs of rivastigmine and memantine (prepared with the help of the Faculty of Pharmacy of Shahid Beheshti University of Medical Sciences). It will be delivered to the researcher in the form of capsules in numbered boxes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

psychosomatic and psychiatric ward of Taleqani hospital

Full name of responsible person

Alireza Shamsi

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2

Recruitment center

Name of recruitment center

Psychiatric ward of Emam-Hossein Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Parniyan Molaee
Position
Psychiatry resident
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Specialist
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Information about the main outcome can be shared.
When the data will become available and for how

long

Access period starts 6 months after the results are published.

To whom data/document is available

Researchers working in academic and scientific institutions.

Under which criteria data/document could be used

For use in meta-analyzes

From where data/document is obtainable

Dr. Alireza Shamsi

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

Written request

Comments