Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of memantin on cognitive performance in patient under electroconvolsive therpy (clinical trial)

Protocol summary

Study aim

مقایسه اثر ممانتین روی عملکرد شناختی بیماران تحت شوک درمانی در دو گروه مقایسه و پلاسبو

Design

Clinical trial with control group, with parallel groups, three blind, randomized

Settings and conduct

Shahid Yahyanejad Hospital in Babol After initial examination, ECT candidates are randomly divided into control and case groups. Patients in the memantine group and patients in the placebo control group are capsules that are filled with ointment and placed in the memantine pill inside the capsule and divided into two groups A and B. None of the patients, researcher or analyst will be aware of the division of the groups. And a third fellow in the A and B segment design, and at the end of the study, identify the groups receiving the placebo and medication.

Participants/Inclusion and exclusion criteria

Entry requirements: 60 patients over the age of 18 years and under age 60 with bipolar disorder psychiatric disorders Non-arrival: aged less than 18 years and over 60 years Kidney disease confirmed Cognitive impairment such as delirium and dementia History of Memantine use 3 months ago before entering the study Patients who are not able to test due to decentralization or distraction Gastrointestinal disturbances and mimentin susceptibility, and during the study or suffer from complications due to intolerance to increase the dose of memantine Patients who receive more than 6 ECT sessions

Intervention groups

In this clinical trial, 60 patients over the age of 18 and under the age of 60 with bipolar disorder psychiatric illnesses will be admitted to the ECT since the beginning of this year. All patients will undergo a full psychiatric assessment and patient disorder will be recorded based on DSM-V.

Main outcome variables

Memantine, cognitive impairment; Electrotherapy; Comparison of memantine effect on cognitive function of patients undergoing shock therapy in two groups; placebo and placebo

General information

Reason for update

Acronym

ect

IRCT registration information

IRCT registration number: **IRCT20170606034348N3**
Registration date: **2019-04-11, 1398/01/22**
Registration timing: **retrospective**

Last update: **2019-04-11, 1398/01/22**
Update count: **0**

Registration date

2019-04-11, 1398/01/22

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 913 121 3171

Email address

a.hamidia@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

2018-05-22, 1397/03/01

Actual recruitment end date
2019-03-11, 1397/12/20
Trial completion date
2019-04-07, 1398/01/18

Scientific title
Effect of memantin on cognitive performance in patient under electroconvolsive therpy (clinical trial)

Public title
Effect of memantin on cognitive performance in patient under electroconvolsive therpy (clinical trial)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
In this clinical trial, 60 patients over the age of 18 and under the age of 60 with bipolar disorder psychiatric illnesses will be admitted to the ECT since the beginning of the year 1396-97.All patients will undergo a full psychiatric assessment and patient disorder is recorded based on DSM-V.
Exclusion criteria:
Age outcomes aged less than 18 years and over 60 years of age, alcohol dependence or drug and drug addiction (except nicotine and caffeine) within 3 months of admission, confirmed kidney disease, epilepsy, back Mental retardation, cognitive impairments such as delirium and dementia, history of memantine use in the past 3 months before entering the study, patients who are unable to perform tests due to distraction , gastrointestinal disturbances and memantine susceptibility, and during Studying or suffering from intolerance to increasing the dose of memantine, as well as patients who receive more than 6 ECT sessions, are excluded be.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, a random number randomization tool was used
Blinding (investigator's opinion)
Triple blinded
Blinding description
After initial examination, ECT candidates are randomly divided into control and case groups. Patients in the memantine group and patients in the placebo control group are capsules that are filled with ointment and placed in the memantine pill inside the capsule and divided into two groups A and B. None of the patients, researcher or analyst will know the grouping of the groups, and the third partner is aware of the division of A and B, and at the end of the work the groups receiving the placebo and the drug will be identified.
Placebo
Used
Assignment
Parallel
Other design features
.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Babol University of Medical Sciences
Street address
Keshavarz Boulevard
City
babol
Province
Mazandaran
Postal code
4713566547
Approval date
2019-03-10, 1397/12/19
Ethics committee reference number
IR.MUBABOL.HRI.REC.1397.296

Health conditions studied

1

Description of health condition studied
Cognitive impairment
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The cognitive ability of the patients will be measured 24 hours before and 24 hours after the ECT session 6, as well as one month after the completion of the ECT using the MMSE (Mini Mental Status Examination) and the Aden Brook Cognitive Examination Test. We will use the MMSE Iranian version in this study.
Timepoint
24 hours before and 24 hours after the 6th session of the ECT, as well as one month after the completion of the ECT
Method of measurement

Eden Brook MMSE (Mini Mental Status Examination)

Secondary outcomes

1

Description
as well as one month after the completion of the ECT using the MMSE (Mini Mental Status Examination) and the Aden Brook Cognitive Examination Test. We will use the MMSE Iranian version in this study.
Timepoint
One month after the completion of the ECT
Method of measurement
In this research we will use the Iranian version of MMSE and Eden Brooke.

Intervention groups

1

Description
Control group: Control group: Memantine in the case group starts 24 hours before the start of the study with a dose of 10 mg and will increase to 20 mg in a week. And will continue until the end of session 6 of the ECT. The placebo control group will be given. The cognitive ability of the patients will be measured 24 hours before and 24 hours after the ECT session 6, as well as one month after the ECT atomic, using the MMSE (Mini Mental Status Examination) and the Aden Brook Cognitive Examination Test. We will use the MMSE Iranian version in this study.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Yahyanejad Hospital
Full name of responsible person
Dr. Angela Hamidia
Street address
Mostafa Khomeini Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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
Babol University of Medical Sciences
Full name of responsible person
Dr. Angela Hamidia
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
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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

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

Title and more details about the data/document

abstract Full article file

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in academia and academia or those working in the industry can apply for them

Under which criteria data/document could be used

Maintaining a moral charter Refer to the present article in their project

From where data/document is obtainable

Babol university of medical science Yahyanejad hospital Angela Hamidia MD

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

access period 6 months after printing the results Researchers working in academia and academia

Comments