

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The comparison of memantine and melatonin in alleviation of cognitive impairment after ECT

Protocol summary

Study aim

The aim of present study is to comparison effect of memantine and melatonin on cognitive disorder after doing Electroconvulsive therapy (ECT)

Design

Clinical trial double blind randomized

Settings and conduct

Inpatient ward of psychiatric in Baqiyatallah hospital

Participants/Inclusion and exclusion criteria

Inclusion criterion: patients needed ECT. Exclusion criteria: history of sensitivity to memantine or melatonin; pregnancy or lactation.

Intervention groups

Comparison effect of melatonin 3 mg per day and memantine 5 mg per day in memory decrease induced of ECT

Main outcome variables

MMSE questionnaire score

General information

Reason for update

Acronym

ECT Electro convulsive therapy

IRCT registration information

IRCT registration number: **IRCT20121021011192N8**

Registration date: **2019-10-02, 1398/07/10**

Registration timing: **retrospective**

Last update: **2019-10-02, 1398/07/10**

Update count: **0**

Registration date

2019-10-02, 1398/07/10

Registrant information

Name

Mohammad Abbasinazari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8887 3704

Email address

m_abbasi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of memantine and melatonin in alleviation of cognitive impairment after ECT

Public title

The comparison of Memantine and Melatonin on memory

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing ECT in Baqhiatallah hospital Taking consent form

Exclusion criteria:

Patients with history of allergy to melatonin Patients with history of allergy to memantine Addict patients

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

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

En simple, block, individual, using table of random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, principle investigator, healthcare providers (Physicians, nurses) who care for participants, data collector and outcome assessors during the trial will be blinded. Preparing memantine and melatonin in blind format will be done just by one responsible co-researcher has no involvement in running study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University

Street address

School of Pharmacy, Nyayesh cross, Valiasr street

City

Tehran

Province

Tehran

Postal code

1996835113

Approval date

2018-10-15, 1397/07/23

Ethics committee reference number

IR.IAU.PS.REC.1397.335

Health conditions studied

1

Description of health condition studied

Cognitive disorder

ICD-10 code

F99

ICD-10 code description

Mental disorder, not otherwise specified

Primary outcomes

1

Description

Change in Mimi Mental Status Exam (MMSE) score

Timepoint

1 month

Method of measurement

questionnaire of Mimi Mental Status Exam (MMSE)

Secondary outcomes

empty

Intervention groups

1

Description

Group 1 Intervention: use of 5 mg per day memantine aboreyhan for 1 month

Category

Treatment - Drugs

2

Description

Group 2 Intervention: use of 3 mg per day melatonin nature made USA for 1 month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychotherapy clinic of Baqiyatallah hospital

Full name of responsible person

Taleb Badri

Street address

Molasadra street, Sheikh Bahaii junction

City

Tehran

Province

Tehran

Postal code

3458025321

Phone

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Email

farshadpharm@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nima Naderi

Street address

School of Pharmacy, Nyayesh cross, Valiasr street

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nimanaderi@yahoo.com

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

Mohammad Abbasi Nazari

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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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

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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Undecided - It is not yet known if there will be a plan to make this available
When the data will become available and for how long
Undecided - It is not yet known if there will be a plan to

make this available
To whom data/document is available
only available for people working in academic institutions
Under which criteria data/document could be used
Undecided - It is not yet known if there will be a plan to make this available
From where data/document is obtainable
Email to m_abbasi@sbmu.ac.ir Mohammad Abbasinazari
What processes are involved for a request to access data/document
Only sending an email
Comments