

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Efficacy of Memantine on Cognitive Performance of Patients Under Electro Convulsive Therapy

Protocol summary

Summary

The purpose of this study is investigation of the effectiveness of memantine on cognitive performance in patients treated with ECT. This study is a double-blind placebo- controlled clinical trial. The population of the study is patients that candidate for ECT who are between 18 and 60 years of age and 4 to 12 sessions of ECT that agree with informed consent and do not have dependency or abuse of alcohol or drugs (except nicotine or caffeine) within 3 months prior admission, do not have contraindications for Memantine, seizures, delirium, dementia, do not have cognitive impairment, do not be in lactation or pregnancy phase, and no history of taking Memantine from 3 months prior to admission and drug that have interaction with Memantine. Sample size has been (in both intervention and control groups) evaluated 20 cases. Intervention in this study is Memantine or placebo in intervention and control groups 48 hours before ECT until 24 hours after completion of ECT course, which is used with 10 mg two times a day . outcome variables of the study are cognitive status, short-term memory, concentration and precision that will be checked with mini mental state examination scores(MMSE) and digit span test figures (one of the subtests of the Wechsler).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013072314122N1**

Registration date: **2013-12-28, 1392/10/07**

Registration timing: **na**

Last update:

Update count: **0**

Registration date

2013-12-28, 1392/10/07

Registrant information

Name

Azad Maroufi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 1666 0025

Email address

maroufi@muk.ac.ir

Recruitment status

Not enough for processing

Funding source

kurdistan University of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2014-03-21, 1393/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Memantine on Cognitive Performance of Patients Under Electro Convulsive Therapy

Public title

Efficacy of Memantine on Cognitive Performance of Patients Under Electro Convulsive Therapy

Purpose

Treatment

Inclusion/Exclusion criteria

This study was done on patients in Sanandaj in 1392 in Qods hospital admissions and physician elected to receive ECT. Inclusion criteria: Patients between 60-18 years of age who are candidates for ECT; Patient or legal guardian to sign an informed consent form; Number of

ECT sessions is between 4 to 12 sessions; Location is the city of Sanandaj. Exclusion criteria: Abuse or dependence on alcohol and drugs during the 3 months prior to admission (excluding nicotine or caffeine); Proven kidney disease (Renal Failure proven); Epilepsy; Mental Retardation based on clinical evaluation Resident Project; Delirium, Dementia and Cognitive disorders; Pregnancy and lactation; Use of Memantine than 3 months prior to admission; Patients who are receiving Thiazide diuretics; History of allergic symptoms and side effect with Memantine.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kurditan University of Medical Sciences

Street address

Pasdaran Ave., Quds hospital campus

City

Sanandaj

Postal code

13446-66177

Approval date

2013-09-18, 1392/06/27

Ethics committee reference number

14,21648

Health conditions studied

1

Description of health condition studied

Mental and behavioural disorders

ICD-10 code

F20-F21-F2

ICD-10 code description

Schizophrenia, schizotypal and delusional disorders

2

Description of health condition studied

Mental and behavioural disorders

ICD-10 code

F30-F31-F3

ICD-10 code description

Mood [affective] disorders

3

Description of health condition studied

Mental and behavioural disorders

ICD-10 code

F40-F41-F4

ICD-10 code description

Neurotic, stress-related and somatoform disorders

4

Description of health condition studied

Mental and behavioural disorders

ICD-10 code

Disorders

ICD-10 code description

F60-F61-F62-F63-F64-F65-F66-F67-F68-F69

5

Description of health condition studied

Mental and behavioural disorders

ICD-10 code

Disorders

ICD-10 code description

F60-F61-F62-F63-F64-F65-F66-F67-F68-F69

6

Description of health condition studied

Mental and behavioural disorders

ICD-10 code

F99

ICD-10 code description

Unspecified mental disorder

Primary outcomes

1

Description

Cognitive function

Timepoint

ECT prior to and after completion of the

Method of measurement

MMSE and Digit Span Test

Secondary outcomes

1

Description

duration of the seizure

Timepoint

During ECT sessions

Method of measurement

View and review patient records

2

Description

Delayed onset seizure

Timepoint

Electric convulsive therapy during hospital stay

Method of measurement

patients visit and file check

Intervention groups

1

Description

cap memantine first day 5 mg capsule twice a day and the second day, three times a day, then 10 mg capsule twice a day (morning and night) until the end of ECT treatment

Category

Treatment - Drugs

2

Description

Placebo capsules, starch capsules 5 mg in the morning and evening of the first day, second day morning noon and night and then 10 mg capsules morning and night until the end of ECT treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghods hospital in Sanandaj

Full name of responsible person

Dr Azad Maroufi, psychiatrist, professor of Kurdistan University of Medical Sciences

Street address

Shohadaye Niruye Entezami Boulvar, Sanandaj

City

sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Fardin Gharibi, Research Assistant

Street address

Research of Kurdistan University of Medical Sciences

City

Sanandaj

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kurdistan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Azad Maroufi

Position

Psychiatrist Kurdistan University of Medical Sciences

Other areas of specialty/work

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Pasdaran street below the Pardis, Ghods hospital, Sanandaj

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Person responsible for scientific inquiries

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Kurdistan University of Medical Sciences

Full name of responsible person

Azad Maroufi

Position

Psychiatrist

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

Person responsible for updating data**Contact****Name of organization / entity**

Kurdistan University of Medical Sciences

Full name of responsible person

Azad Maroufi

Position

Psychiatrist Kurdistan University of Medical Sciences

Other areas of specialty/work