

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of Memantine on cognitive profile of patients with epilepsy: A randomized, double-blind, placebo-controlled clinical trial

Protocol summary

Study aim

The effect of Memantine on cognitive status of epileptic patients

Design

Randomized double blinded two arm parallel group with control group clinical trial

Settings and conduct

Eligible patients will take the FAB, MMSE and MoCA examination and after randomization to 2 groups, participants and doctors will be blinded to the treatment. After taking the patients' history a sealed envelope; contained code A or B; will be given to them, which determine for the pharmacist to give which drug (Memantine and placebo have the same cover) to the patients

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients between 15-65 years old
Epileptic patients with mild to moderate cognitive impairment who received anti-epileptic drugs over 6 months
Seizure episodes less than four times a month
Exclusion criteria: Progressive neurological disorder, major psychiatric disorder and mental retardation
Severe medical illnesses such as renal failure; Pregnancy or breastfeeding; Patients within inter-ictal phase (2 weeks); Patients with more than 4 seizure episodes over a month; Adverse drug effect; Drug allergy or intolerance

Intervention groups

Initiation of 5 mg oral Memantine tablet once a day and continuing the same dose for 8 weeks, after that 10 mg oral Memantine tablet once a day with caution for the rest 8 weeks. So the intervention period was 4 month. In the other group, oral placebo was given once a day for 16 weeks.

Main outcome variables

Prescription of Memantine as a treatment for improving epileptic patients' cognitive status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121110011424N5**

Registration date: **2019-09-25, 1398/07/03**

Registration timing: **retrospective**

Last update: **2019-09-25, 1398/07/03**

Update count: **0**

Registration date

2019-09-25, 1398/07/03

Registrant information

Name

Abbas Tafakhori

Name of organization / entity

Iranian Center of Neurological Research

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

2018-08-23, 1397/06/01

Actual recruitment end date

2019-02-20, 1397/12/01

Trial completion date

2019-02-20, 1397/12/01

Scientific title

Effects of Memantine on cognitive profile of patients with epilepsy: A randomized, double-blind, placebo-controlled clinical trial

Public title

Effect of Memantine on epileptic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients between 15-65 years old Epileptic patients who received anti epileptic drugs over 6 months with mild to moderate cognition impairment Seizure episodes less than four times a month

Exclusion criteria:

Progressive neurologic disease, psychiatric disorders, and mental retardation Severe medical illnesses such as renal failure Pregnancy or breast feeding Patients during inter-ictal phase (2 weeks) Patients with seizure episodes more than four times a month adverse drug effect drug allergy or intolerance

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were divided into 2 groups with sequentially numbered method(randomization with the random number builder software)

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and doctors are both blinded about the treatment. After taking the patient's history, the researcher give a sealed envelope including code A (Memantine) or code B (placebo) to the patient. Then, patient will give that wrapped envelope to the pharmacist and received the assigned drug (drug A or B which are kept in the same cover from the company). The pharmacist will record patients' name and drug codes without knowing the type of the drug and this information will be kept until the end of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417744361

Approval date

2018-07-24, 1397/05/02

Ethics committee reference number

IR.TUMS.IKHC.REC.1397.052

Health conditions studied

1

Description of health condition studied

Epilepsy

ICD-10 code

G40

ICD-10 code description

Epilepsy and recurrent seizures

Primary outcomes

1

Description

Cognitive status score according to MMSE (Folstein mini-mental state examination) criteria

Timepoint

Before intervention and 16 weeks after intervention

Method of measurement

Asking questions of MMSE (Folstein mini-mental state examination)

2

Description

Cognitive status score according to FAB (Frontal Assessment Battery)

Timepoint

Before intervention and 16 weeks after intervention

Method of measurement

Asking questions of FAB (Frontal Assessment Battery)

3

Description

Cognitive status score according to MoCA (Montreal Cognitive Assessment)

Timepoint

Before intervention and 16 weeks after intervention

Method of measurement

Asking questions of MoCA (Montreal Cognitive Assessment)

4

Description

Adverse events

Timepoint

16 weeks after intervention

Method of measurement

Adverse events form

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 5 mg Memantine oral tablet once a day for 8 weeks and then 10 mg once a day for another 8 weeks with caution

Category

Treatment - Drugs

2

Description

Control group: placebo once a day for 16 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Abbas Tafakhori

Street address

Neurology clinic of Imam Khomeini hospital, end of Keshavarz boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

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?

No

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Abbas Tafakhori

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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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

No - There is not 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

Clinical and demographic data will be available

When the data will become available and for how long

When data was published

To whom data/document is available

Public

Under which criteria data/document could be used

For scientific use only

From where data/document is obtainable

Email (PI)

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

PI approval

Comments