Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 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
Abbas Tafakhori
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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
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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