Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of Donepezil and Memantine on improving cognitive function in patients with temporal lobe epilepsy

Protocol summary

Study aim
Evaluation and comparison of the effects of Donepezil and Memantine on improving cognitive function in patients with temporal lobe epilepsy

Design
This study is a non-randomized clinical trial without control group with parallel groups. Epileptic patients referred to clinic are divided into two groups in decussate form. The first group receives Donepezil (10 mg daily) and the secong group receives Memantine (10 mg daily) for 16 weeks. After treatment, patient's cognitive function is evaluated and compared between two groups.

Settings and conduct
In this study patients with temporal lobe epilepsy referred to Alzahra and Kashani hospital clinics are selected and divided into two groups in decussate way. The firs group and second groups are treated with Donepezil and Memantine, respectively. Cognitive function is evaluated in both groups before and after intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1)Age between 18-55 years; 2)Having temporal lobe epilepsy; 3)Have no other neurological disease; 4)Use no medication for treating cognitive disorders; 5)patient's willingness to participate in this study. Exclusion criteria: 1)Mental retardation; 2)Having progressive neurological disease; 3)Having sensitivity to Donepezil or Memantine.

Intervention groups
In this study, in the first group 10 mg Donepezil is prescribed daily for 16 weeks. In second group, 10 mg Memantine is prescribed daily for 16 weeks.

Main outcome variables
The score of Montreal Cognitive Assessment test

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180113038344N1**
Registration date: **2018-03-18, 1396/12/27**
Registration timing: **prospective**

Last update: **2018-03-18, 1396/12/27**
Update count: **0**

Registration date
2018-03-18, 1396/12/27

Registrant information

Name
Marjan Oustad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3785 0698

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oustadmarjan@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-21, 1397/01/01

Expected recruitment end date
2019-03-21, 1398/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of Donepezil and Memantine on improving cognitive function in patients with temporal lobe epilepsy

Public title
Effect of Donepezil and Memantine on improving cognitive function
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having age between 18-55 years Having temporal lobe epilepsy Have no other neurological disease Use no medications for treating cognitive disorders willingness to participate in this study
Exclusion criteria:
Having mental retardation Having progressive neurological disease Having sensitivity to Memantine or Donepezil
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Science
Street address
Hezar jarib street, Isfahan University of Medical Science
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2017-05-22, 1396/03/01
Ethics committee reference number
IR.MUI.REC.1396.3.530

Health conditions studied

1

Description of health condition studied
Temporal lobe epilepsy
ICD-10 code
G40.2
ICD-10 code description
Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures

Primary outcomes

1

Description
The score of Montreal Cognitive Assessment test
Timepoint
Before and immediately after intervention
Method of measurement
Montreal Cognitive Assessment questionnaire

Secondary outcomes

1

Description
Incidence of sensitivity to Memantine
Timepoint
During intervention
Method of measurement
observation

2

Description
Incidence of sensitivity to Donepezil
Timepoint
During intervention
Method of measurement
observation

Intervention groups

1

Description
Intervention group: In this group 10 mg Donepezil is prescribed daily for 16 weeks that is produced by Jalinous Pharmacological Company.
Category
Treatment - Drugs

2

Description
Intervention group: In this group 10 mg Memantine is prescribed daily for 16 weeks that is produced by Sobhan Pharmacological Company.
Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra Hospital

Full name of responsible person
Mohammadreza Najafi

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2

Recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Marjan Oustad

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Neuroscience

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available