

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 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 second 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 first 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

Email address

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

Isfahan

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

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Mohammadreza Najafi

Street address

Alzahra Hospital, Sofe Street

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2

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ahmad Movahedian

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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 scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mohammadreza Najafi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neuroscience

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

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neuroscience

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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