

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the effect of Donepezil on Cerebral Blood Flow Velocity in Alzheimer's disease

Protocol summary

Summary

This clinical trial was carried out in department of Neurology in Alzahra Hospital (Isfahan University of Medical Sciences) from March 5, 2008 to July 28, 2009 and was performed on AD patients in two groups of case and control, each consisting of 11 patients. The inclusion criterion was age between 50 and 80 years, and the exclusion criteria included history of stroke, nontreated hypertension, diabetes mellitus, smoking during the past 10 years, hypercholesterolemia and taking AChEi drugs one month prior to the study. Methods: Out of 30 patients, 22 patients completed the study and included for the study. This clinical trial was performed on AD patients in two groups of case and control, each consisting of 11 patients. The case group who received Donepezil medication was examined by TCD before (baseline), after four weeks of oral treatment with 5mg per day Donepezil and a further four weeks of 10mg per day Donepezil, administered orally. The control group were AD patients who did not receive any medications effective on AD and were examined by TCD only once. Peak systolic (PSV), end-diastolic (EDV) and mean flow (MFV) velocities of posterior cerebral artery (PCA) and middle cerebral artery (MCA) were assessed by TCD. Also, mini-mental state examination (MMSE) was carried out.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812183518N1**
Registration date: **2010-05-20, 1389/02/30**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-05-20, 1389/02/30

Registrant information

Name

Mehdi Shishegar

Name of organization / entity

Isfahan University of Medical Sciences, Isfahan, Iran

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences, Isfahan, Iran.

Expected recruitment start date

2008-04-03, 1387/01/15

Expected recruitment end date

2009-07-21, 1388/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of Donepezil on Cerebral Blood Flow Velocity in Alzheimer's disease

Public title

Evaluating the effect of Donepezil on Cerebral Blood Flow Velocity in Alzheimer's disease

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria : age between 50 and 80 years, and the exclusion criteria : history of stroke, nontreated

hypertension, diabetes mellitus, smoking during the past 10 years, hypercholesterolemia and taking AchEI drugs one month prior to the study.

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Age

From **50 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

In this study, 19 patients with AD were initially allocated to the case group. Out of the 19 patients, five did not continue participating in the study after four weeks of treatment with Donepezil, one patient in the second round of follow up did not cooperate to perform TCD and two were excluded due to discontinuation of the drug because of agitation side effect and finally 11 patients remained in the case group. Also, 11 patients with AD were allocated to the control group. The case group comprised patients who were treated with Donepezil; and TCD was performed every four weeks. The control group consisted of Alzheimer's disease patients who did not use any medication; and inclusion and exclusion criteria similar to those for the case group were applied to this group, and TCD was performed only once for them.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences, Isfahan, Iran

Street address

faculty of medicine, Isfahan University of Medical Sciences, Isfahan.

City

Isfahan

Postal code

817467573 صندوق پستی

Approval date

empty

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Alzheimer's disease

ICD-10 code

G30

ICD-10 code description

Alzheimer's disease

2

Description of health condition studied

Alzheimer's disease

ICD-10 code

F00

ICD-10 code description

Dementia in Alzheimer's disease

Primary outcomes

1

Description

Mini Mental State Examination

Timepoint

before, 1 month and 2 months after intervention

Method of measurement

with checklist

2

Description

Peak systolic flow velocity

Timepoint

before, 1 month and 2 months after intervention

Method of measurement

Transcranial Doppler sonography

3

Description

Peak diastolic flow velocity

Timepoint

before, 1 month and 2 months after intervention

Method of measurement

Transcranial Doppler sonography

4

Description

mean flow velocity

Timepoint

before, 1 month and 2 months after intervention

Method of measurement

Transcranial Doppler sonography

Secondary outcomes

empty

Intervention groups

1

Description

In control group no drug was used and only one time carry out TCD

Category

N/A

2

Description

Donepezil(oral) tab with dose of 5mg/d for 1 month and then 5mg/d every 12 hours for another 1 month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Mehdi Shishegar MD

Street address

Department of Neurology, Isfahan Neuroscience Research Center, Alzahra hospital, Sofeh St, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences, Isfahan, Iran

Full name of responsible person

Mojtaba Akbari

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faculty of medicine, Isfahan University of Medical Sciences, Isfahan, Iran

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Grant name

از معاونت پژوهشی دانشگاه علوم پزشکی اصفهان

Grant code / Reference number

388239

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

Yes

Title of funding source

Isfahan University of Medical Sciences, Isfahan, Iran

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

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Full name of responsible person

Mehdi Shishegar MD

Position

Resident of Neurology

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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