

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1668 4444

###### Email address

shishegar@resident.mui.ac.ir

##### 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.

388239

### 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

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Isfahan University of Medical Sciences, Isfahan, Iran

##### Full name of responsible person

Mojtaba Akbari

##### Street address

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

##### City

Isfahan

#### 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

Isfahan University of Medical Sciences, Isfahan, Iran

##### Full name of responsible person

Mehdi Shishegar MD

##### Position

Resident of Neurology

##### Other areas of specialty/work

##### Street address

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## Person responsible for scientific inquiries

#### Contact

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Isfahan University of Medical Sciences, Isfahan, Iran

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#### Phone

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#### Fax

## 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*