# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## Comparison the effects of Donepezil, Galantamine,Rivastigmine and Memantine on transcranial Doppler sonography and MMSE in patients with vascular dementia.

## Protocol summary

**Study aim**

Comparison the changes of transcranial Doppler sonography (TCD) and Mini mental state examination (MMSE) in patients with vascular dementia treated with Rivastigmine, Memantine , Galantamine and Donepezil .

**Design**

This study is double blinded clinical trial that conducted on 44 patients with vascular dementia in Shafa hospital in Kerman in 1397. Patients are divided into 4 groups of 11 patients. Each group is treated with either Donepezil , memantine, galanthamine, or rivastigmine. TCD is performed on starting and after 3 months of treatment. MMSE is also evaluated before and after intervention.

**Settings and conduct**

This study is double blinded clinical trial that conducted on 44 patients with vascular dementia in Shafa hospital in Kerman in 1397. Patients are divided into 4 groups of 11 patients. Each group is treated with either Donepezil , memantine, galanthamine, or rivastigmine. TCD is performed on starting and after 3 months of treatment. MMSE is also evaluated before and after intervention.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria for the study is the patients with vascular dementia.Patients are excluded from the study if there is any underlying diseases other than Diabetes, hypertention,hyperlipidemia and ischemic heart disease, including history of depression,memory and speech impairment,taking any medication such as sedative drugs and substance abuse, except for the control of underlying diseases.

**Intervention groups**

Goup1:patients with vascular dementia treated with Rivastigmine. Goup2:patients with vascular dementia treated with Donepezil. Goup3patients with vascular dementia treated with Galantamine. Goup4:patients with vascular dementia treated with Memantine.

**Main outcome variables**

Measurement of mean flow velocity of Anterior cerebral artery(ACA),Middle cerebral artery(MCA),Posterior cerebral artery(PCA)

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20181210041912N1**
Registration date: **2019-01-14, 1397/10/24**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-14, 1397/10/24**
Update count: **0**

**Registration date**

2019-01-14, 1397/10/24

**Registrant information**

**Name**

Ali Farzanmoghadam

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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+98 35 3725 1254

**Email address**

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2018-12-22, 1397/10/01

**Expected recruitment end date**

2019-06-21, 1398/03/31

**Actual recruitment start date**

empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparison the effects of Donepezil, Galantamine,Rivastigmine and Memantine on transcranial Doppler sonography and MMSE in patients with vascular dementia.

**Public title**
Comparison the effects of Donepezil, Galantamine,Rivastigmine and Memantine on vascular dementia.
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients with vascular dementia in Kerman city
**Exclusion criteria:**
Having any underlying condition other than diabetes, hypertension, hyperlipidemia, and ischemic heart disease, including history of depression and memory and speech impairment. Use of any medication, such as sedative medicines and substance abuse, except medicines for controlling diabetes, hypertension, hyperlipidemia, and ischemic heart disease.
**Age**
No age limit
**Gender**
Both

**Phase**
2
**Groups that have been masked**

- Investigator
- Outcome assessor

**Sample size**
Target sample size: **44**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
In this study, 44 patients with vascular dementia referring to a neurologist were randomly divided into 4 groups of 11 patients. The randomization method is simple and How to create a sequence. is random.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
This study was carried out for patients with vascular dementia at the onset of ultrasound and MMSE intervention and then referred to one of the contributors who are unaware of the type of medication. After receiving the code, the patient is treated with one of the medications in the uncertain packing (A, B, C, D) until the end of the intervention, which is repeated in the above procedures.
**Placebo**
Not used
**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Kerman University of Medical Sciences
**Street address**
Campus of the University of Medical Sciences, the center of seven Alavi Gardens, Kerman
**City**
Kerman
**Province**
Kerman
**Postal code**
7616913555
**Approval date**
2018-12-10, 1397/09/19
**Ethics committee reference number**
IR.KMU.AH.REC.1397.093

## Health conditions studied

### 1

**Description of health condition studied**
Vascular Dementia
**ICD-10 code**
I63
**ICD-10 code description**
occlusion and stenosis of cerebral and precerebral arteries (including truncus brachiocephalicus), resulting in cerebral infarction

## Primary outcomes

### 1

**Description**
Transcranial Doppler Sonography
**Timepoint**
Performing transcranial doppler sonography at the beginning of the study and three months after taking any of the donepezill, memantine, galanthamine or rivastigmine drugs
**Method of measurement**
Doppler Sonography machine

## Secondary outcomes

### 1

**Description**
Mini Mental State Examination

**Timepoint**
Measurement of the MMSE at the beginning of the study and three months after the onset of consumption, which of the drugs donepezil, memantine, galantamine or rivastigmine
**Method of measurement**
By number from zero to thirty

## Intervention groups

### 1

**Description**
Intervention group: Donpezil starts at 5mg / day and increases to 10mg / day within two weeks and lasts up to three months.
**Category**
Treatment - Drugs

### 2

**Description**
Intervention group: Rivastigmine starts at 1.5mg twice daily and increases to 3mg twice a week within a week.
**Category**
Treatment - Drugs

### 3

**Description**
Intervention group: Memantine starts at 5mg daily and increases to 10mg per day in one week.
**Category**
Treatment - Drugs

### 4

**Description**
Intervention group: Galanthambon is given 8mg daily.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Shafa hospital
**Full name of responsible person**
Farhad Iranmanesh
**Street address**
Shafa hospital,Kosar Blvd
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Kerman University of Medical Sciences
**Full name of responsible person**
Farhad Iranmanesh
**Street address**
Research and Technology Assistance, Somayeh Intersection (Tahmasebabad), Ibn Sina Avenue, .Kerman,Iran
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fpp_farhad@yahoo.com
**Web page address**
http://kmu.ac.ir/fa/vcrt
**Grant name**
Deputy of Research and Technology of Kerman University of Medical Sciences
**Grant code / Reference number**
411389339391
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Kerman 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**
Kerman University of Medical Sciences
**Full name of responsible person**
Farhad Iranmanesh

**Position**
Professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Neurology
**Street address**
Shafa Hospital, Kosar Blvd, Kerman
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## Person responsible for scientific inquiries

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Assistant professor
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## Person responsible for updating data

**Contact**
**Name of organization / entity**
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**Full name of responsible person**
Ali Farzanmoghadam
**Position**
Resident
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Medical doctor
**Other areas of specialty/work**
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**Phone**
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**Email**
alifarzan57@yahoo.com

## 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**
Yes - There is 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**
The results of transcranial doppler sonography that shares all the data after unidentifiable individuals.
**When the data will become available and for how long**
After completing the transcranial doppler sonography
**To whom data/document is available**
Faculty Members of Medical Universities across Iran
**Under which criteria data/document could be used**
With written request for reuse of files
**From where data/document is obtainable**
Postcode: Kerman, Kowsar Blvd, Shafa Hospital, Ali Farzan Moghadam Email:alifarzan57@yahoo.com phone number:09132512862
**What processes are involved for a request to access data/document**
The written and formal request of the applicant who has been approved by the research assistant at the university of the applicant's workplace will be sent no later than one week later.
**Comments**