

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 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, hypertension, 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

Group1: patients with vascular dementia treated with Rivastigmine. Group2: patients with vascular dementia treated with Donepezil. Group3: patients with vascular dementia treated with Galantamine. Group4: 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)

Phone

+98 35 3725 1254

Email address

alifarzan57@yahoo.com

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 donepezil, 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: Donepezil 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

City

Kerman

Province

Kerman

Postal code

۷۶۱۸۷۵۱۱۵۱

Phone

+98 34 3211 5780

Fax

+98 34 3211 5783

Email

shafahospital@kmu.ac.ir

Web page address

http://kmu.ac.ir/fa/sh

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

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3226 3719

Fax

+98 34 3226 3857

Email

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
City
Kerman
Province
Kerman
Postal code
۷۶۱۸۷۵۱۱۵۱
Phone
+98 34 3211 5780
Email
fpp_farhad@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Kave Shafiee
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
Street address
Shafa Hospital, Kosar Blvd, Kerman
City
Kerman
Province
Kerman
Postal code
۷۶۱۸۷۵۱۱۵۱
Phone
+98 34 3211 5780
Email
kshafiee@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Ali Farzanmoghadam
Position

Resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurology
Street address
Shafa hospital, Kosar Blvd
City
Kerman
Province
Kerman
Postal code
۷۶۱۸۷۵۱۱۵۱
Phone
+98 35 3725 1254
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