

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effectiveness of Rivastigmine and Donepezil on cognitive disorders in patients with moderate stroke

Protocol summary

Study aim

The effect on cognitive disorders in patients with moderate stroke

Design

This study is a clinical trial with three case-control and control groups that 165 patients with moderate brain injury from Isfahan hospitals will be included in the study.

Settings and conduct

No blinding was performed in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient consent to enter the study
Patients with moderate concussion with an GCS of 12-8.
Exclusion criteria: Consciousness coefficient greater than 12
History of any brain disorders in the patient
Patients with Acetylcholinesterase contraindications

Intervention groups

In the first group: Rivastigmine is prescribed for one month at a dose of 1.5 mg and then the dose of the drug will be increased by 3.5 mg. This drug is prescribed for patients in this group for up to three months. In the second group: Donepezil is prescribed for 1 month at a dose of 5 mg, after which the dose will be increased by 10 mg. This drug is prescribed for patients in this group for up to three months.

Main outcome variables

Impact on the patient's cognitive disorders

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210819052232N1**

Registration date: **2021-11-07, 1400/08/16**

Registration timing: **prospective**

Last update: **2021-11-07, 1400/08/16**

Update count: **0**

Registration date

2021-11-07, 1400/08/16

Registrant information

Name

Iman Salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3685 7150

Email address

iman_salehi19@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of Rivastigmine and Donepezil on cognitive disorders in patients with moderate stroke

Public title

Effectiveness of Rivastigmine and Donepezil on cognitive disorders

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patient consent to enter the study Patients with moderate concussion with an GCS of 12-8.

Exclusion criteria:
 Consciousness coefficient greater than 12 History of any brain disorders in the patient Patients with Acetylcholinesterase contraindications

Age
 No age limit

Gender
 Both

Phase
 3

Groups that have been masked
No information

Sample size
 Target sample size: **165**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Random function of Excel software based on patient file number will be used for randomization. Patients with moderate concussion were included in the Excel program based on the file number and were divided into three groups of case, control and control based on the random button. There were three groups of 55 people in total. By entering the file number in Excel program, then the random number is selected from the data analysis command. This study has 3 groups that can be numbered from 1 to 3, respectively. We also want 55 people in each group. As a result, sequences 1 to 3 should be repeated 55 times each time. It is clear that the repetition of each number occurs once in each group, so select 1 for repeating each number and 55 for repeating the sequence. In this way, 165 units will be produced.

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 Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib St., Shiraz Gate

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-08-01, 1400/05/10

Ethics committee reference number

IR.MUI.MED.REC.1400.350

Health conditions studied

1

Description of health condition studied

Cognitive disorder

ICD-10 code

G31.84

ICD-10 code description

Mild cognitive impairment, so stated

Primary outcomes

1

Description

Reduce cognitive impairment

Timepoint

After discharge and three months after

Method of measurement

MMSE, NUCog, Moca questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Rivastigmine is prescribed for one month at a dose of 1.5 mg and then the dose will be increased by 3.5 mg. This drug is prescribed for patients in this group for up to three months

Category

Rehabilitation

2

Description

Intervention group: Donpezil is given at a dose of 5 mg for one month, after which the dose will be increased by 10 mg. This drug is prescribed for patients in this group for up to three months.

Category

Rehabilitation

3

Description

Control group: Patients are in the control group treated with placebo, which is very similar to the drug and receives up to three months later.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra Hospital

Full name of responsible person

Mehdi Shafiei

Street address

Isfahan University of Medical Sciences, Hezar Jarib St.,

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

Mehdishafiei82@gmail.com

2**Recruitment center****Name of recruitment center**

Kashani Hospital

Full name of responsible person

Mehdi Shafiei

Street address

Kashani ST

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3233 0091

Email

kashani@mui.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjuye Javanmardi

Street address

Isfahan University of Medical Sciences, hezar jarib S.T

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

research@mui.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

1

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

Mehdi Shafiei

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

Isfahan University of Medical Sciences, Hezar Jarib St.,

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

Mehdishafiei82@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Mehdi Shafiei

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery
Street address
Al-Zahra hospital, Sofeh St.,Isfahan,Iran
City
Isfahan
Province
Isfahan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
Mehdishafiei82@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Iman Salehi
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurosurgery
Street address
Al-Zahra hospital, Sofeh St.,Isfahan,Iran
City
Isfahan

Province
Isfahan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
iman_salehi19@yahoo.com

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

Undecided - It is not yet known if there will be a plan to make this available

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