

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Comparative Investigation efficacy of cognitive rehabilitation and donepezil on memory, attention, quality of life and depression in patients with multiple sclerosis.

Protocol summary

Summary

Objective: Comparative Investigation efficacy of cognitive rehabilitation and donepezil on memory, attention, quality of life and depression in patients with multiple sclerosis. This clinical Trial with pretest-posttest plan is done in four groups and double blind for subjects and researchers. Statistical population of 80 patients with multiple sclerosis referred to MS clinics of Isfahan Kashani hospital that are available and were selected based on inclusion criteria. Allocation of subjects to four groups of 20 persons, including Group A (intervention with cognitive rehabilitation therapy), Group B (No any Intervention), Group C (Intervention with donepezil) and group D (placebo) were random and after determining dysfunction cognitive patients by means of Autobiographical memory test, prospective and retrospective memory questionnaire, the Early Motor questionnaire, Digit span test for attention questionnaire, quality of life questionnaire and Beck for primary care questionnaire to determine the level of depression in the pre-test stage, for group A 20hours cognitive rehabilitation in 3 month period, for group C prescribed donepezil 10mg daily for 3 month and for group D placebo daily for 3 month is done. Then once again cognition status of subjects on four groups will analyze by using the above-mentioned questionnaire at post-test stage and compare the results of the intervention in groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042227522N1**

Registration date: **2016-06-02, 1395/03/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-02, 1395/03/13

Registrant information

Name

Mohammad Mahdi Shahpouri

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3629 1050

Email address

shahpouri@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2016-05-30, 1395/03/10

Expected recruitment end date

2016-06-30, 1395/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Investigation efficacy of cognitive rehabilitation and donepezil on memory, attention, quality of life and depression in patients with multiple sclerosis.

Public title

Comparative Investigation efficacy of cognitive rehabilitation and donepezil on memory, attention, quality of life and depression in patients with multiple sclerosis.		City Isfahan
		Postal code
		Approval date 2016-02-03, 1394/11/14
		Ethics committee reference number IR.MUI.REC.1395.3.1008
Purpose Treatment		
Inclusion/Exclusion criteria Inclusion criteria: definite diagnosis of MS according to the McDonald criteria by neurologist ; ability to participate in the interview and convey information and their experiences ; desire to participate in the study and necessary cooperation and motivation for interview ; absence of chronic disease other than multiple sclerosis ; age between 20 and 60 years ; having at least read and write education ; lack of renal and hepatic diseases ; non-use of anticholinergic drugs ; patients with Expanded Disability Status Scale up to 5/5 on the criteria of John Kurtzke ; patients with mild to moderate level of memory performance ; study of depression of subjects according to Beck for Primary Care questionnaire to verify the inclusion and omission of severe depression. Exclusion criteria: loss of each conditions during the study inclusion ; lack of desire to continue this research collaboration ; inability to participate in therapy sessions regularly ; relapses of disease during the intervention period that lead to hospitalization in the hospital.		Health conditions studied 1 Description of health condition studied Multiple Sclerosis ICD-10 code G35-G37 ICD-10 code description Demyelinating diseases of the central nervous system
Age From 20 years old to 60 years old		Primary outcomes 1 Description Memory Timepoint Before Intervention & 3 month after Intervention Method of measurement Autobiographical Memory Test , The Prospective and Retrospective Memory Questionnaire , The Early Motor Questionnaire
Gender Both		2 Description Attention Timepoint Before Intervention & 3 month after Intervention Method of measurement Digit Span Test
Phase N/A		3 Description Depression Timepoint Before Intervention & 3 month after Intervention Method of measurement Beck for Primary Care questionnaire
Groups that have been masked No information		4 Description Quality of Life Timepoint Before Intervention & 3 month after Intervention Method of measurement Quality of Life 54 questionnaire
Sample size Target sample size: 80		
Randomization (investigator's opinion) Randomized		
Randomization description		
Blinding (investigator's opinion) Double blinded		
Blinding description		
Placebo 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 Hezar Jerib St, Isfahan		Secondary outcomes empty

Intervention groups

1

Description

Intervention group 1 : 20 hours Cognitive rehabilitation in 3 month period

Category

Rehabilitation

2

Description

Intervention group 2 : Tab Donepezil 10mg daily for 3 month

Category

Treatment - Drugs

3

Description

Intervention group 3 :Tab Placebo daily for 3 month

Category

Placebo

4

Description

Control group : No any Intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

MS Clinic of Isfahan Kashani Hospital

Full name of responsible person

Mohammad Mahdi Shahpouri

Street address

Kashani St, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor Of Research, Isfahan University of Medical Sciences

Full name of responsible person

Dr Nematbakhsh

Street address

Hezar Jerib St, Isfahan University Of Medical Sciences, Isfahan, Iran

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor Of Research, Isfahan University of Medical Sciences

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 ,
Neurosciences Research Center

Full name of responsible person

Mohammad Mahdi Shahpouri

Position

MD

Other areas of specialty/work

Street address

Azzahra Hospital, Soffeh St, Isfahan, Iran

City

Isfahan

Postal code

Phone

+98 31 3780 7646

Fax

Email

Shahpouri@resident.mui.ac.ir;
Shahpouri2m@gmail.com; Mahdijan2010@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences ,
Neurosciences Research Center

Full name of responsible person

Vahid Shaygannejad

Position

Professor

Other areas of specialty/work

Street address

Azzahra Hospital, Soffeh St, Isfahan, Iran

City

Isfahan

Postal code

Phone

+98 913 313 3550

Fax

Email

Shaygannejad@med.mui.ac.ir

Web page address

Fax

Email

Shahpouri@resident.mui.ac.ir;

Shahpouri2m@gmail.com; Mahdijan2010@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical Sciences, Neurosciences
Research Center

Full name of responsible person

Mohammad Mahdi Shahpouri

Position

MD

Other areas of specialty/work

Street address

Azzahra Hospital, Soffeh St, Isfahan, Iran

City

Isfahan

Postal code

Phone

+98 31 3780 7646

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