

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effect of Memantine on fatigue in patients with Multiple sclerosis: A double-blind randomized controlled clinical trial

Protocol summary

Summary

Objective: Effects of Memantine on fatigue in Multiple sclerosis (MS) patients. Study design: It is a Randomized; double-blind; placebo-controlled; single-center; and Phase 1 clinical trial. Randomization of the study is stratified block randomization (using blocks of 4) based on sex. Study population: They are patients with definite diagnosis of MS based on diagnostic McDonald criteria that receive the standard treatment for MS and have been referred from clinic of neurology of Imam Khomeini Hospital in 1395. Inclusion criteria: A history of multiple sclerosis (MS) for more than one year; Relapsing Remitting (RR) type of MS; Subjective fatigue (grade 3 or 4 of fatigue based on questionnaires); Age of 55-20 years; Expanded Disability Status Scale (EDSS): 0-5; Consent to participate in the study. Exclusion criteria: Use of Modafinil, Ritalin or Amantadine; A history of seizure and kidney disease; Taking selective serotonin reuptake inhibitors (SSRI); Other types of diseases. Sample Size: 64 patients (32 patients in each group). Intervention: intervention group receive 10 mg daily (1 tablet) for one week and then 20 mg daily (2 tablets) until the end of 3 months of study; control group receive 1 tablet of placebo for one week and then 2 tablets of placebo until the end of 3 months of study. Primary outcome: fatigue. Secondary outcomes: Depression; cognitive status and physical disability.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121231362N1**
Registration date: **2017-01-03, 1395/10/14**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-03, 1395/10/14

Registrant information

Name

Mohammad Hossein Harirchian

Name of organization / entity

Iranian center of neurological research

Country

Iran (Islamic Republic of)

Phone

+98 21 6694 8899

Email address

harirchm@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iranian Center of Neurological Research

Expected recruitment start date

2016-10-31, 1395/08/10

Expected recruitment end date

2017-01-29, 1395/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Memantine on fatigue in patients with Multiple sclerosis: A double-blind randomized controlled clinical trial

Public title

Effects of Memantine on fatigue in patients with Multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: A history of multiple sclerosis (MS) for more than one year; Type of MS was Relapsing Remitting (RR); Subjective fatigue (grade 3 or 4 fatigue based on questionnaires); Age of 20-55 years; Expanded Disability Status Scale (EDSS): 0-5; Consent to participate in the study. Exclusion criteria: Use of Modafinil, Ritalin or Amantadine; A history of seizure and kidney disease; Taking selective serotonin reuptake inhibitors (SSRI); Other types of diseases.

Age

From **20 years** old to **55 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Blocking design based on sex

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Tehran University of Medical Sciences

Street address

Keshavarz Blvd

City

Tehran

Postal code

Approval date

2016-10-22, 1395/08/01

Ethics committee reference number

IR.TUMS.IKHC.REC.1395.808

Health conditions studied

1

Description of health condition studied

Multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

fatigue

Timepoint

before intervention, 3 months after start of intervention

Method of measurement

MFIS Questionnaire

Secondary outcomes

1

Description

depression

Timepoint

before intervention, 3 months after start of intervention

Method of measurement

Beck II questionnaire

2

Description

cognitive disorders

Timepoint

before intervention, 3 months after start of intervention

Method of measurement

MACFIMS test

3

Description

disability

Timepoint

before intervention, 3 months after start of intervention

Method of measurement

EDSS test

Intervention groups

1

Description

Intervention group: memantine, 10 mg oral tablet, one per day for the first week and then twice a day for three months

Category

Treatment - Drugs

2

Description

Control group: placebo (exactly the same as the intervention group), oral tablet, one per day for the first week and then twice a day for three months

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian Center of Neurological Research

Full name of responsible person

Mohammad hossein Harirchian

Street address

Iranian Center of Neurological Research, Imam Khomeini Hospital, Keshavarz Boulevard

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian Center of Neurological Research

Full name of responsible person

Farzad Fatehi

Street address

Iranian Center of Neurological Research, Imam Khomeini Hospital, Keshavarz Boulevard

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iranian Center of Neurological Research

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

Iranian Center of Neurological Research

Full name of responsible person

Mohammad hossein Harirchian

Position

Neurologist

Other areas of specialty/work**Street address**

Iranian Center of Neurological Research, Imam Khomeini Hospital, Keshavarz Boulevard

City

Tehran

Postal code**Phone**

+98 21 6694 8899

Fax

+98 21 6658 1558

Email

harirchm@tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iranian Center of Neurological Research

Full name of responsible person

Mohammad hossein Harirchian

Position

Neurologist

Other areas of specialty/work**Street address**

Iranian Center of Neurological Research, Imam Khomeini Hospital, Keshavarz Boulevard

City

Tehran

Postal code**Phone**

+98 21 6694 8899

Fax

+98 21 6658 1558

Email

harirchm@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iranian Center of Neurological Research

Full name of responsible person

Sama Bitarafan

Position

Researcher, MD& PhD

Other areas of specialty/work**Street address**

Iranian Center of Neurological Research, Imam Khomeini Hospital, Keshavarz Boulevard

City

Tehran

Postal code**Phone**

+98 21 6694 8899

Fax

+98 21 6658 1558

Email

Bitarafan@sina.tums.ac.ir; Bitarafans@gmail.com

Web page address

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