# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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
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**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**

Treatment - Drugs

## 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

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

**City**
Tehran

**Grant name**
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**Grant code / Reference number**
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**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**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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*