

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of effectiveness of memantine and vitamin B1 in fatigue of patients with multiple sclerosis

Protocol summary

Study aim

Determining the effect of memantine on fatigue in patients with MS

Design

Patients are assigned to two treatment groups A and B using the method of random blocks (Balance block randomization). The balanced randomization allocation method for the participants in the randomized controlled clinical trial study is the effect of receiving memantine(group A) and placebo (group B) in reducing fatigue.

Settings and conduct

patients with a definite diagnosis of MS (based on McDonald's diagnostic criteria) referring to the neurology clinic of Bo Ali Hospital will be randomly included in the study.The intervention group will receive 5mg daily(1 table) for one week and then 10mg daily(2 tablets) until the end of 3 months of the study. The control group will receive one placebo pill for one week and then 2 placebo pills until the end of 3 month study.

Participants/Inclusion and exclusion criteria

1.Age 20-50 years 2.EDSS between 0-5 3.Relapsing - Remitting MS 4.Level 3 or 4 fatigue based on the questionnaire Patients who do not meet the above conditions are excluded from the study

Intervention groups

60 patients will be included in the study.The intervention group will receive 5 mg daily (1tablet)for one week and then 10 mg daily (2 tablet) until the end of 3 months of the study. The control group will receive one placebo pill for one week and then 2 placebo pills until the end 3 months of the study.

Main outcome variables

Physical aspect of MFIS Base/6m/12m ; Cognitive aspect of MFIS Base/6m/12m ; Psychosocial aspect of MFIS Base/6m/12m ; MFIS total score Base/6m/12m

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240118060725N1**

Registration date: **2024-02-14, 1402/11/25**

Registration timing: **prospective**

Last update: **2024-02-14, 1402/11/25**

Update count: **0**

Registration date

2024-02-14, 1402/11/25

Registrant information

Name

Fateme Jafarichamandani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 4224 8954

Email address

fatemejafari78@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-20, 1403/01/01

Expected recruitment end date

2024-06-21, 1403/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of memantine and vitamin B1 in fatigue of patients with multiple sclerosis

Public title

The effect of memantine on fatigue in patients with Multiple Sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 20-50 years EDSS between 0-5 Relapsing-Remitting MS Grade 3 or 4 fatigue according to the questionnaire

Exclusion criteria:

Use of Modafinil, Ritalin or Amantadine History of seizures or kidney disease Taking selective serotonin reuptake inhibitor (SSRI) Recent attack within the last 3 months Use of Dalaira

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are assigned to two treatment groups A and B using the method of random blocks (Balance block randomization), the size of each block is 10 and the total number of blocks is 5 as 10 and the total number of blocks is 5 as described in the attached table. The balanced in randomization allocation method for the participants in the randomized controlled clinical trial study is the effect of receiving memantine (group A) and placebo (group B) in reducing fatigue. Data will be analyzed in spss software version 23, using descriptive tests such as mean and standard deviation (for continuous quantitative variables such as age) and number and percentage (for qualitative/nominal variables such as gender). The data are analyzed by independent test to check the relationship between quantitative variables between two chi-square to check the relationship between qualitative variables between two groups. A statistically significant level of 5% is considered.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are assigned to two treatment groups A and B using the method of random blocks (Balance block randomization). Balanced randomization allocation method for participants in a randomized controlled clinical trial study on the effect of receiving memantine (group A) and placebo (group B) in reducing fatigue

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Bo Ali St. Bo Ali Sina Hospital

City

Qazvin

Province

Qazvin

Postal code

3413786165

Approval date

2023-12-26, 1402/10/05

Ethics committee reference number

IR.QUMS.REC.1402.276

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

Examining the degree of fatigue based on the Modified Fatigue Impact Scale questionnaire

Timepoint

Comparison of fatigue before and 3 months after starting memantine and placebo

Method of measurement

Modified Fatigue Impact Scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: Memantine 5 mg tablets by Hacim company. First daily for a week, then one every 12 hours

for 3 months and orally. This drug is a competitive NMDA glutamate antagonist.

Category

Treatment - Drugs

2

Description

Control group:Vitamin B1 100 mg tablets by Hacim company.First daily for a week , then one every 12 hours for 3 months and orally.This medicine is a water-soluble vitamin

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu Ali Sina Hospital

Full name of responsible person

Fateme Jafari Chamandani

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seyyed Mehdi Mirhashemi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Fateme Jafari Chamandani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

Fateme Jafari Chamandani

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no customer information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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