Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 ebove 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 Dalfira
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 continious 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

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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 updating data

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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