Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The effects of lisdexamphetamine dimesylate on multiple sclerosis patients with fatigue: A randomized, double blind, placebo-control clinical trial

Protocol summary

Study aim

Studying the effectiveness of lisdexamfetamine dimesylate in relieving fatigue in patients with MS.

Design

To randomly assign the samples to two groups of 25, the block method will be used. The sampling method will be available sampling.

Settings and conduct

The study is being conducted at the MS Clinic of the Bu Ali Sina Medical Center in Sari. Patients will initially receive lisdexamfetamine at a dose of 30 mg daily, and then, if tolerated, will be increased by 20 mg every 2 weeks to a maximum dose of 70 mg, and then continue for 4 weeks. The drug and placebo will be placed in identical, identical drug packages from Tekajeh Company, which are coded based on a randomized table. Each code will be assigned to a specific patient.

Participants/Inclusion and exclusion criteria

The inclusion criteria : adults over 18 years old with multiple sclerosis according to the McDonald 2017 criteria and EDSS less than 5.5 and according to the Fatigue MIFS>33 criteria; individuals had informed consent to enter the study. The exclusion criteria: severe depression; hypothyroidism; severe anemia (Hb‹ 9 g/dl); breastfeeding or pregnancy; history of ischemic cva or cardiovascular disease; decreased renal function; presence of an MS attack within the past month; uncontrolled blood pressure (BP ≥ 160/100 mm Hg); concomitant use of medications that affect fatigue; history of drug, psychotropic, and alcohol abuse; concomitant use of MAOI and SSRI; presence of narcolepsy; presence of psychosis; history of seizures; history of vascular disorders

Intervention groups

Patients were given lisdexamfetamine at doses of 30, 50, 70, and placebo, and the effect on fatigue was examined.

Main outcome variables

the improvement in their fatigue and quality of life was assessed and recorded based on the Kurtzke Functional Systems Scores (MSFC, FSS), PSQI, MFI, SF-36, Fatigue Severity Scale (FSS) of Sleep Disorders, and HADS.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241129063892N2**
Registration date: **2024-12-21, 1403/10/01**
Registration timing: **retrospective**

Last update: **2024-12-21, 1403/10/01**
Update count: **0**

Registration date

2024-12-21, 1403/10/01

Registrant information

Name
Mohammad Baghbanian
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-18, 1403/08/28

Expected recruitment end date

2024-11-30, 1403/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of lisdexamphetamine dimesylate on multiple sclerosis patients with fatigue: A randomized, double blind, placebo-control clinical trial

Public title

The effects of lisdexamphetamine dimesylate on multiple sclerosis patients with fatigue

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults with multiple sclerosis according to the McNeeshan 2017 criteria EDSS less than 5.5 MIFS>33 according to the Fatigue criterion.

Exclusion criteria:

Severe depression Hypothyroidism Severe anemia (Hb‹ 9 g/dl) Breastfeeding or pregnancy History of ischemic cerebrovascular accident or cardiovascular disease Decreased kidney function Presence of an MS attack within the past month Uncontrolled blood pressure (blood pressure ≥ 160/100 mm Hg) Concomitant use of medications that affect fatigue History of drug, psychotropic, and alcohol abuse Concomitant use of monoamine oxidase inhibitors and serotonin reuptake inhibitors Presence of narcolepsy The presence of psychosis History of seizures History of vascular disorders

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomly assign the samples to two groups of 25, the block method will be used. For this purpose, 13 blocks of four will be considered. The possible blocks are TTCC, TCTC, TCCT, CCTT, CTCT, CTTC, where T is for the intervention group and C is for the control group. Numbers will be generated randomly (with the RANDBETWEEN command in Excel software) and according to the generated values, one of the blocks will be selected and the samples will be allocated. The sampling method will be available sampling.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug and placebo are placed in identical, specific drug packages from Tekajeh Company, which are coded based on a randomized table. Each code will be assigned to a specific patient. The patients receiving the drug, the assistant evaluating the study variables, and the prescribing neurologist are unaware of the type of drug they are receiving.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Ms clinic, boali hosbital, pasdaran blvd,sari

City

Sari

Province

Mazandaran

Postal code

48158 38477

Approval date

2024-11-13, 1403/08/23

Ethics committee reference number

IR.MAZUMS.REC.1403.373

Health conditions studied

1

Description of health condition studied

Fatigue in multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Fatigue

Timepoint

Beginning of study, weeks 4, 6, 8

Method of measurement

Kurtzke Functional Systems Scores) MSFC,FSS(و PSQI، MFI،SF-36 ، Fatigue Severity Scale (FSS) of Sleep

Disorders ، HADS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For patients, the drug Lysdexamfetamine dimesylate is initially started at a dose of 30 mg daily, and then, if the patient tolerates it, it is increased by 20 mg every 2 weeks to a maximum dose of 70 mg, and then continued for 4 weeks.
Category
Treatment - Drugs

2

Description
Control group: For patients, the placebo drug Lysdexamfetamine dimesylate is initially started at a dose of 30 mg daily, and then, if the patient tolerates it, it is increased by 20 mg every 2 weeks to a maximum dose of 70 mg, and then continued for 4 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
MS Clinic, Bu Ali Sina Medical Training Center, Sari
Full name of responsible person
Negar Heidari Rostami
Street address
Boo'Ali hospital,pasdaran Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Ahmad ali Enaiati
Street address
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Phone
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Web page address
https://www.mazums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Seyad Mohammad Baghbanian
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
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Person responsible for updating data

Contact

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Neurology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Participants' personal data is shared in its entirety.

When the data will become available and for how long
Access begins 6 months after results are published.

To whom data/document is available
Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used
People for the purpose of re-reading or comparing data

From where data/document is obtainable
By email to the following address: Mohammadbaghbanian@gmail.com

What processes are involved for a request to access data/document
The application will be reviewed and responded to within two to four months after the applicant submits their documents.

Comments