

# 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 lisdexamphetamine 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 lisdexamphetamine 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  $\geq$  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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 911 151 8209

##### Email address

mohammadbaghbanian@gmail.com

##### 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( , PSQI, MFI,SF-36 , Fatigue Severity Scale (FSS) of Sleep

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: For patients, the drug Lisdexamfetamine 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 Lisdexamfetamine 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,pasdarán Blvd

##### City

Sari

##### Province

Mazandaran

##### Postal code

48158 38477

##### Phone

+98 11 3334 3011

##### Fax

##### Email

Mohammadbaghbanian@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Ahmad ali Enaiati

#### Street address

Boo'Ali hospital,Pasadaran Blvd

#### City

Sari

#### Province

Mazandaran

#### Postal code

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#### Phone

+98 11 3334 3011

#### Email

Mohammadbaghbanian@gmail.com

#### 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

##### Street address

Boo'Ali hospital, Pasdarán Blvd

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##### Province

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##### Postal code

48158 38477

##### Phone

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##### Email

Mohammadbaghbanian@gmail.com

## Person responsible for scientific

## **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

**Street address**

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Negar Heidari Rostami

**Position**

Residente

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurology

**Street address**

Maryam apartment, fadak 2 alley, fadak street

**City**

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**Province**

Mazandaran

**Postal code**

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**Phone**

+98 11 3324 4273

**Email**

Negar\_heidari72@yahoo.com

## **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**