Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of the efficacy of lisdexamfetamine on fatigue in patients with multiple sclerosis: A randomized, double-blind, placebo-controlled study

Protocol summary

Study aim
Assessment of the efficacy of lisdexamfetamine compared to placebo on the improvement of fatigue in patients with multiple sclerosis (MS) according to MFIS (Modified Fatigue Impact Scale) questionnaire

Design
A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 52 patients. Random allocation software was used for randomization.

Settings and conduct
This study is a double-blind randomized clinical trial with a placebo arm that investigates the effect of lisdexamfetamine on fatigue in patients with MS. In this study, the researcher attends 5 days a week in MS Clinic of Sina Hospital. The drug and placebo are coded by a person who is not involved in patient recruitment, monitoring and data analysis in the study and are given to the researcher in the same packaging. The drug and placebo codes will be kept with this person until the end of the study. The studied patients are assigned to one of the two drug or placebo groups based on random block in a double-blind manner (so that the doctor, researcher and patient do not know the type of drug).

Participants/Inclusion and exclusion criteria
MS patients with a total score of MFIS greater than 33 are entered in the study. Patients who suffer from fatigue due to secondary causes are excluded from the study. Severe hepatic and renal failure, pregnancy, breastfeeding, history of drug abuse are other exclusion criteria.

Intervention groups
Intervention group: 26 patients are treated with lisdexamfetamine for one month. The dosage of the drug is 30 mg once a day for one month and if tolerated, it is increased to 50 mg daily in the second month. Control group: 26 patients are treated with placebo for two months.

Main outcome variables
Improvement of fatigue in patients with MS according to MFIS questionnaire

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230125057221N1**
Registration date: **2023-05-04, 1402/02/14**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-04, 1402/02/14**
Update count: **0**

Registration date
2023-05-04, 1402/02/14

Registrant information
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Rayehe Tavajohi
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-04-21, 1402/02/01
Expected recruitment end date
2024-04-20, 1403/02/01
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessment of the efficacy of lisdexamfetamine on fatigue in patients with multiple sclerosis: A randomized, double-blind, placebo-controlled study

Public title
Assessment of the effect of lisdexamfetamine on fatigue in patients with multiple sclerosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of MS based on 2017 McDonald criteria Age 18 to 45 years Informed and written consent of the patient EDSS≤5.5 Total score obtained from MFIS greater than 33 Not changing the type or dose of DMT in the last three months
Exclusion criteria:
Pregnancy or breastfeeding Allergy to the drug or formulation ingredients Severe renal failure (ClCr < 30 ml/min/1.73m2) moderate to severe liver failure (Child Pugh B, C) history of attack or receiving pulse dose of corticosteroid in the last one month or during the study Changing the used medication during the study Abuse of alcohol and drugs such as opium or psychoactive agents simultaneous use or last two weeks use of amantadine, modafinil, methylphenidate, dexamphetamine suffering from any untreated thyroid disorder (TSH outside the normal range) Vitamin D level less than 20 ng/ml A patient with anemia (hemoglobin less than 14 g/dL in men or less than 12 g/dL in women) Patients who suffer from severe fatigue and need symptomatic treatment due to ethical considerations History of cardiovascular or cerebrovascular disease such as IHD, ACS, heart failure, any cerebral ischemia and bleeding, and uncontrolled blood pressure (SBP ≥160 or DBP ≥100) Concurrently suffering from any anxiety disorder, severe depression or psychosis for which they are receiving pharmacotherapy History or simultaneous suffering from epilepsy Taking monoamine oxidase inhibitors in the last 14 days
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients with MS will be divided into two groups using block randomization method of size 4. The random sequence was created using random allocation software. Concealment is also guaranteed using the block randomization method. The drug and placebo are coded by a person who is not involved in patient admission, patient monitoring and data analysis in the study and are provided to the researcher in the same packaging. The drug and placebo code will be kept with this person until the end of the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study is double-blind, and for this purpose, the participants, the main researcher, and the health and medical personnel who are responsible for the care of the patient do not know the type of medicine the patient received. Before the start of the study, the drug and placebo are coded by a person who is not involved in patient recruitment, patient monitoring, and data analysis, and are given to the researcher in completely identical packaging. The drug and placebo codes will be kept with this person until the end of the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of The Institute of Pharmaceutical Sciences-Tehran University of Medical
Street address
Faculty of pharmacy, Tehran University of Medical Sciences, 16 Azar Ave., Enghelab Sq.
City
Tehran
Province
Tehran
Postal code
1417614411
Approval date
2023-01-21, 1401/11/01
Ethics committee reference number
IR.TUMS.TIPS.REC.1401.103

Health conditions studied

1

Description of health condition studied
Multiple sclerosis related fatigue

ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Fatigue score in MFIS questionnaire
Timepoint
beginning of the study, 1 month and 2 month after study arrival
Method of measurement
MFIS questionnaire

Secondary outcomes

1

Description
blood pressure
Timepoint
beginning of the study, 1 month and 2 month after study arrival
Method of measurement
blood pressure monitor

2

Description
heart rate
Timepoint
beginning of the study, 1 month and 2 month after study arrival
Method of measurement
heart rate monitor

3

Description
weight
Timepoint
beginning of the study, 1 month and 2 month after study arrival
Method of measurement
scale

4

Description
anxiety score
Timepoint
beginning of the study, 1 month and 2 month after study arrival
Method of measurement
Hamilton Anxiety Rating Scale

5

Description
sleep quality score
Timepoint
beginning of the study, 1 month and 2 month after study arrival
Method of measurement
Pittsburgh Sleep Quality Index

6

Description
depression score
Timepoint
beginning of the study and 2 month after study arrival
Method of measurement
beck depression inventory 2

Intervention groups

1

Description
Intervention group: 26 patients in this group are treated for 2 months with lisdexamfetamine manufactured by Tadbir Kalaye Jam Company. The starting dose is 30 mg daily for one month. If tolerated in the second month, the dose of the drug is increased to 50 mg daily.
Category
Treatment - Drugs

2

Description
Control group: 26 patients in this group are treated with a placebo completely similar to the original drug manufactured by Tadbir Kalaye Jam Company. The starting dose is 30 mg daily for one month. If tolerated in the second month, the dose of the drug is increased to 50 mg daily.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
MS Clinic of Sina Hospital
Full name of responsible person
Hooshyar Honarmand
Street address
Sina hospital, Hassan Abad sq., Imam Khomeini st.
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hosp_sina@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Hossein Ghahremani
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headquarters of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd
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pharmacy@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
3
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

2

Sponsor
Name of organization / entity
Research Center for Rational Use of Drugs
Full name of responsible person
Soha Namazi
Street address
No.92, next to Tejarat Bank, Karim Khan Zand Ave., Haft Tir Sq.
City
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Email
snamazi@sina.tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Center for Rational Use of Drugs
Proportion provided by this source
97
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
Tehran University of Medical Sciences
Full name of responsible person
Rayehe Tavajohi
Position
clinical pharmacy resident
Latest degree
Medical doctor
Other areas of specialty/work
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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
According to the items mentioned in the informed consent form, the information of the patients will not be distributed.
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
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
Title and more details about the data/document
Patient demographic data as well as variable outcome data will be shared after patients are unidentifiable.
When the data will become available and for how long
The data will be available after the end of the study and is expected to be available on the Internet from May 2024.
To whom data/document is available
Medical activists
Under which criteria data/document could be used
The data will be available after obtaining the necessary permits from researchers.
From where data/document is obtainable
Tehran University of Medical Sciences
What processes are involved for a request to access data/document
A written request for data must be submitted by the individual.
Comments