Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of amantadine and dalfampridine efficacy in multiple sclerosis patients with fatigue

Protocol summary

Study aim
Efficacy evaluation of dalfampiridine on MS fatigue
Efficacy evaluation of Amantadine on MS fatigue
evaluation of dalfampiridine and amatadine tolerabilty
Evaluation of Quality of life following dalfampiridine and amantadine administration

Design
A randomized parallel group clinical trial with blinded outcomes assessment of 80 patients. Randomization will be done according permuted block way.

Settings and conduct
This study is a randomized and double blind clinical trial will be conducted at MS clinic in Ibne Sine hospital in patients with fatigue of MS. Principle investigators, researcher and participants will be blinded.

Participants/Inclusion and exclusion criteria
Adult patients ware aged more than 18 years with MS according Mcdonald criteria 2017 and have FATIGUE SCORE OF MIFS›33 WILL BE RECRUITED. Exclusion criteria: severe depression, hypothyroidism, Severe anemia (Hb‹ 9 g/dl), pregnancy or breast feeding, IHD OR cardiovascular disease, real insufficiency, MS exacerbation within one months before, uncontrolled blood pressure (more than 160/100 mm Hg), co-administration of effective drugs on fatigue, alcohol, recreational or substance abuse hisory, MAOIs use, history of narcolepsy, psychosis and seizure.

Intervention groups
Intervention: dalfampiridine 10 mg q 12 hour for 8 weeks
Control: Amantadine 100 mg q 12 hour for 8 weeks

Main outcome variables
Fatigue and quality of life according improvement to MFIS and quality of life questionnaire and tolerability of therapeutic regimens.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190804044429N2**
Registration date: **2020-06-12, 1399/03/23**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-12, 1399/03/23**
Update count: **0**

Registration date
2020-06-12, 1399/03/23

Registrant information
Name
Monireh Ghazaeian
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
2020-06-09, 1399/03/20

Expected recruitment end date
2021-06-10, 1400/03/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of amantadine and dalfampridine efficacy in multiple sclerosis patients with fatigue

Public title

Amantadine and dalfampiridine effects on multiple sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Adult patients were aged more than 18 years Patients with multiple sclerosis according to Mcdonald criteria 2017 and EDSS less than 5.5 MS patients with at least fatigue score of 33 according to MFIS

Exclusion criteria:
Severe depression Hypothyroidism Severe anemia (Hb‹ 9 g/dl) Pregnancy or breast feeding Ischemic heart disease or cardiovascular disease Renal insufficiency MS exacerbation within 30 days before Uncontrolled blood pressure (BP more than 160/100 mm Hg) use of other effective treatment on fatigue Alcohol, recreational and substance abuse history Monoamine oxidase inhibitors (MAOIs) use Narcolepsy history Psychosis history Seizure history

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

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

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
A master randomization schedule was prepared by a person not associated with the study who used permuted blocks of random numbers. The medicine bottles and identical placebo were prepared by a pharmaceutical manufacturer Randomization was incorporated in the serially numbered bottles containing drug or placebo by person not involved with the study according to random numbers. The number of the bottle corresponded with the number of the patient.

Blinding (investigator's opinion)
Double blinded

Blinding description
participants and principle investigator and statistic staff will be blinded.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mazandaran University of Medical Science

Street address
Ibn Sina Hospital, Pasdaran Blvd, Sari, Mazandaran.

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Sari

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Postal code
4815733971

Approval date
2020-05-27, 1399/03/07

Ethics committee reference number
IR.MAZUMS.REC.1399.325

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
Fatigue improvement

Timepoint
At weeks 4, and 8

Method of measurement
MFIS questionnaire

Secondary outcomes

1

Description
Quality of life

Timepoint
At weeks 4 , 8

Method of measurement
SF-36 Questionnaire

2

Description
Tolerable of therapeutic regimen

Timepoint
Weekly

Method of measurement
History taking

Intervention groups

1

Description
Intervention group: dalfampridine 10 m q12 hour for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: Amantadine 100 mg q 12 hour for 8 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ibn Sina hospital
Full name of responsible person
Monireh Ghazaeian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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
Monireh Ghazaeian
Position
Assistant Professor
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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

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

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

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The results of trial including analysis data and method of the study

When the data will become available and for how long
At the time of publication, the data of the study will be available.

To whom data/document is available
academic researchers, medical team and scientific institutes

Under which criteria data/document could be used
For research and practical purposes

From where data/document is obtainable
Dr. Monireh Ghazaeian, Faculty of pharmacy, Mazandaran University of Medical Sciences.

What processes are involved for a request to access data/document
The scientific responsible person of the study will reply to the request within 10 days.

Comments