

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

Study aim

Efficacy evaluation of dalfampridine on MS fatigue
Efficacy evaluation of Amantadine on MS fatigue
evaluation of dalfampridine and amantadine tolerability
Evaluation of Quality of life following dalfampridine 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 were 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, renal 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 history, MAOIs use, history of narcolepsy, psychosis and seizure.

Intervention groups

Intervention: dalfampridine 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 MIFS 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

Country

Iran (Islamic Republic of)

Phone

+98 21 8863 6864

Email address

ghazaeianm@gmail.com

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.

City

Sari

Province

Mazandaran

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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Ibn Sina hospital, Pasdaran Blvd, Sari, Mazandaran province.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

Street address

Vice Chancellor for Research, Mazandaran University of Medical Sciences, Joybar 3way , Sari, Iran.

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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

Latest degree

Ph.D.

Other areas of specialty/work

Clinical pharmacy

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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