Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of Therapeutic Effect of Amantidine and Modafinil in Fatigue Related Multiple Sclerosis Patients in Hamedan M.S Clinic (Neshat)

Protocol summary

Study aim
The aim of the present study is to compare the therapeutic effects of amantidine and Modafinil in fatigue related multiple sclerosis in Neshat clinic (Hamedan).

Design
This study will be a double blind clinical trial . This study will be performed in parallel on two groups of patients (Amantidine as control group and Modafinil group).

Settings and conduct
This study is a double blind clinical trial that will be performed at Nashat MS clinic of Hamedan. The attending physician, evaluating neurology resident and patients will be unaware of the types of medication which patients are taking. Patients will be divided into intervention group or modafinil group (200mg/day) and control group or amantadine group(100 mg/day) based on which they will receive the drugs for three months.

Participants/Inclusion and exclusion criteria
Patients of Multiple Sclerosis (Age:16-55) which suffer from fatigue and do not have history of systemic disease are included in the study and patients who smoke or have history of psychosis were excluded from the study.

Intervention groups
Group1 control group with Amantadine :which will be received 100 mg daily in 3 month Group 2 intervention group with Modafinil: which will received 200 mg daily in 3 month

Main outcome variables
Fatigue rate based on FSS questionnaire

General information

Reason for update

Acronym
MS

IRCT registration information
IRCT registration number: **IRCT20210511051267N1**
Registration date: **2021-06-22, 1400/04/01**
Registration timing: **prospective**
Last update: **2021-06-22, 1400/04/01**
Update count: **0**

Registration date
2021-06-22, 1400/04/01

Registrant information

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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
2021-07-21, 1400/04/30

Expected recruitment end date
2023-02-09, 1401/11/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Therapeutic Effect of Amantidine and Modafinil in Fatigue Related Multiple Sclerosis Patients in Hamedan M.S Clinic (Neshat)

Public title
Comparison of Therapeutic Effect of Amantidine and Modafinil in Fatigue Related Multiple Sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age(16-55) Fatigue related to MS Satisfaction for participation in the study
Exclusion criteria:
Narcolepsy Sleep apnea Major systemic disorder late use of Drowsiness and fatigue drugs Smoker Clinical history of thyroid, renal, cardiovascular disorders and diabetes and hepatitis Depression History of psychotic diseases

Age
From **16 years** old to **55 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, we will use the method of balanced block randomization (block size: Four). For this purpose, we prepare four sheets of paper. On the two sheets, we write the I meaning "Intervention" and on the other two sheets we write the P meaning "Placebo". Mix the sheets together, and place them on the desk drawer. When referring to any of the eligible patients, one of the sheets was randomly taken out and based on this sheet, I or P was assigned to one of the two groups of intervention (Modafinil recipient) or comparison (Amantadine recipient). Extracted tabs will not be returned to the drawer until all four tabs have been extracted. After randomly pulling out all four sheets, all the sheets are returned to the drawer and the above procedure will be continued for the next four patients until the desire sample size (150 patients) is reached.

Blinding (investigator's opinion)
Double blinded

Blinding description
The Executors of the research project (Attend and evaluating neurology resident) and statistical analysis colleague and also the patients will be unaware of the types of the drugs for each treatment group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hamedan University of Medical Sciences

Street address
Daneshgah Street, Hamedan University of Medical Sciences, Hamedan, Iran

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Hamedan

Province
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Postal code
6517838736

Approval date
2021-05-01, 1400/02/11

Ethics committee reference number
IR.UMSHA.REC.1400.119

2

Ethics committee

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Postal code
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Approval date
2021-05-01, 1400/02/11

Ethics committee reference number
IR.UMSHA.REC.1400.119

Health conditions studied

1

Description of health condition studied
Fatigue related to multiple sclerosis

ICD-10 code
G35

ICD-10 code description
Multiple scle

Primary outcomes

1

Description
Fatigue rate based on FSS questionnaire(fatigue severity scale)

Timepoint
At the beginning of the study and after three months of receiving the drugs

Method of measurement
In this study fatigue will be evaluated by standard fatigue severity scale questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:treatment groups
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Neshat Rehabilitation clinic
Full name of responsible person
Masoud Ghiasian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Deputy for Research of Hamedan 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
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Position
Resident of neurology
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Other areas of specialty/work
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Person responsible for updating data

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

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

Analytic Code

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

Data Dictionary

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