

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

Name

Masoud Ghiasian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0703

Email address

m.ghiasian@umsha.ac.ir

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

City

Hamedan

Province

Hamadan

Postal code

6517838736

Approval date

2021-05-01, 1400/02/11

Ethics committee reference number

IR.UMSHA.REC.1400.119

2**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

City

Hamedan

Province

Hamadan

Postal code

6517838736

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

Street address

Neshat clinic,Javan Blvd,Saidiyeh Street,Near
Tizhiooshan high school, Hamedan,Iran

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۹۳۳۴۷۹

Phone

+98 81 3821 8657

Fax

Email

m.ghiasian@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Masoud Ghiasian

Street address

Shahid Beheshti Hospital,Ghaem Square,Abasabad
Road,Hamedan, Iran

City

Hamedan

Province

Hamadan

Postal code

6517953371

Phone

+98 81 3838 0703

Email

m.ghiasian@umsha.ac.ir

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

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Maryam Arab

Position

Resident of neurology

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

Street address

Shahid Beheshti Hospital, Ghaem square, Abbas Abad
road, Hamedan, Iran

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۹۵۳۳۷۱

Phone

+98 81 3838 0703

Email

Drkhazaei@umsha.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Masoud Ghiasian

Position

Associate professor of neurology

Latest degree

Subspecialist

Other areas of specialty/work

Neurology

Street address

Shahid Beheshti Hospital, Ghaem square, Abbas Abad
road, Hamedan, Iran

City

Hamedan
Province
Hamadan
Postal code
۶۵۱۷۹۵۳۳۷۱
Phone
+98 81 3838 0703
Email
m.ghiasian@umsha.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Maryam Arab
Position
Resident of neurology
Latest degree
Medical doctor
Other areas of specialty/work
Neurology
Street address
Shahid Beheshti Hospital, Abbas Abad road,
Hamedan, Iran
City
Hamedan
Province
Hamadan

Postal code
۶۵۱۷۹۵۳۳۷۱
Phone
+98 81 3838 0703
Email
Drkhazaei@umsha.ac.ir

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