

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Ondansetron versus Amantadine on fatigability in patients with multiple sclerosis: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of Ondansetron versus Amantadine on fatigability in patients with multiple sclerosis

Design

This is a randomized clinical trial, phase II, in which 104 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with multiple sclerosis who will refer to Sina Hospital during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years; Multiple sclerosis; Complaining of fatigability The ability to walk without assistance for at least 100 meters; FSS score of equal to or greater than 28 Exclusion criteria: Systemic disease such as cardiovascular diseases, infection, thyroid disease, or vasculitis

Intervention groups

Intervention group: Tablet Ondansetron 4 mg twice a day for 4 weeks Control group: Capsule Amantadine 100 mg twice a day for 4 weeks

Main outcome variables

Assessing the fatigability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N250**

Registration date: **2018-11-20, 1397/08/29**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-20, 1397/08/29**

Update count: **0**

Registration date

2018-11-20, 1397/08/29

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-06, 1397/08/15

Expected recruitment end date

2019-01-05, 1397/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Ondansetron versus Amantadine on fatigability in patients with multiple sclerosis: a randomized clinical trial

Public title

Effects of Ondansetron versus Amantadine on fatigability in patients with multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 65 years; Multiple sclerosis; Complaining of fatigability The ability to walk without assistance for at

least 100 meters; FSS score of equal to or greater than 28

Exclusion criteria:

Systemic disease such as cardiovascular diseases, infection, thyroid disease, or vasculitis

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2018-11-03, 1397/08/12

Ethics committee reference number

IR.UMSHA.REC.1397.500

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

Assessing the fatigability

Timepoint

Before and 4 weeks after treatment

Method of measurement

Using a standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Tablet Ondansetron 4 mg twice a day for 4 weeks

Category

Treatment - Drugs

2

Description

Control group: Capsule Amantadine 100 mg twice a day for 4 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Ashkan Karvan

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

City

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6517838695

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+98 81 3827 4184

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karevanashkan2@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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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

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

Ashkan Karvan

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Dr. Mojtaba Khazaei

Position

Neurologist

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

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Person responsible for updating data

Contact**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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