

# 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

##### Email address

poorolajal@umsha.ac.ir

#### 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.

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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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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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info.research@umsha.ac.ir

**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**

Hamedan University of Medical Sciences

**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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**Email**

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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