Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 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
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Name of organization / entity
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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

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Province

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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

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Sponsors / Funding sources

1

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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
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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