Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Therapeutic effect of co-administration of Amantadine and Aspirin on fatigue in patients with multiple sclerosis: a randomized placebo-controlled double-blind study

Protocol summary

Summary

Fatigue is recognized as one of the most disabling and frequent symptoms of multiple sclerosis (MS). Amantadine appears to have some proven ability to alleviate the fatigue in MS. The aim of this study is to assess the efficacy of co-administration of amantadine and aspirin for the treatment of fatigue in multiple sclerosis. Forty-five ambulatory patients aged 20–50 years with a diagnosis of MS, a stable disability level ≤6 on the Kurtzke extended disability status scale (EDSS), and a mean score ≥4 on the fatigue severity scale (FSS) will eligible for the 6 weeks, a double-blind clinical trial. Intervention group will receive Aspirin, 500 mg oral tablet, once daily for 42 days and Amantadine,100-mg oral capsule, once daily for 42 days. Control group will receive Amantadine, 100-mg oral capsule, once daily for 42 days and oral placebo tablet for 42 days. Efficacy will evaluated by using the FSS.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112208430N3**
Registration date: **2012-01-15, 1390/10/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-01-15, 1390/10/25

Registrant information

Name

Farhad Iranmanesh

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Neuroscience Reserch Center of Kerman

Expected recruitment start date

2008-06-19, 1387/03/30

Expected recruitment end date

2009-08-23, 1388/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic effect of co-administration of Amantadine and Aspirin on fatigue in patients with multiple sclerosis: a randomized placebo-controlled double-blind study

Public title

Effect of co-administration of Amantadine and Aspirin on fatigue in patients with multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Definite diagnosis of multiple sclerosis; age between 20-50 years; disability scour ≤6 on the extended disability status scale patients; fatigue score ≥4 on the fatigue severity scale. Exclusion criteria: Patients with current or recent (within 2 months ago) use of medications or allergy to asprin or amantadin.

Age
From **20 years** old to **50 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences
Street address
Shafa street
City
Kerman
Postal code
Approval date
2007-05-12, 1386/02/22
Ethics committee reference number
1/86/ک

Health conditions studied

1

Description of health condition studied
Multiple scerosis
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Fatigue Severity Scale
Timepoint
Before intervention,30 days after intervention,42days after intervention
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Aspirin,500 mg oral tablet, once daily for 42 days and Amantadine,100-mg oral capsule , once daily for 42 days.
Category
Treatment - Drugs

2

Description
Control group:Amantadine,100-mg oral capsule , once daily for 42 days and oral placebo tablet for 42 days .
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa hospital
Full name of responsible person
Akbar Hamzei Moghaddam
Street address
Shafa hospital, Shafa street
City
Kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman Neuroscience Reserch Center
Full name of responsible person
Korosh Divsalar
Street address
Jahad street
City
Kerman
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Kerman Neuroscience Reserch Center

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman Neuroscience Research Center

Full name of responsible person

Akbar Hamzei Moghaddam

Position

Professor of Neurology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty