

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 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 be 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 be 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

+98 34 1226 2629

Email address

fpp_farhad@yahoo.com

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 score ≤ 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 aspirin or amantadine.

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

1/86/5

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**

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
Street address
Jahad street
City
Kerman
Postal code
7618751151
Phone
+98 34 1246 7139
Fax
+98 34 1211 5803
Email
a_hamzehei@kmu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman university of Medical Sciences
Full name of responsible person
Behnaz Sedighi
Position
Associate professor of Neurology
Other areas of specialty/work
Street address
Shafa hospital

City
Kerman
Postal code
7618751151
Phone
+98 34 1211 5780
Fax
+98 34 1211 5803
Email
behnaz_sedigh@gmail.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Farhad Iranmanesh
Position
Associate professor of Neurology
Other areas of specialty/work
Street address
Shafa hospital
City
Kerman
Postal code
7618751151
Phone
00893412115780
Fax
+98 34 1211 5803
Email
fpp_farhad@yahoo.com
Web page address

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