

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effect of amantadine and coenzymeQ10 on the fatigue of the Multiple Sclerosis patients

Protocol summary

Summary

Comparison of the effect of amantadine and coenzymeQ10 on the fatigue of the Multiple Sclerosis patients Inclusion criteria : Informed consent form and questionnaire filling; FSS greater than or equal to 4.0 Exclusion criteria:Use of sedative-hypnotic drugs in the last 2 months;Pregnancy or lactation; Congestive heart failure;kidney or liver disease; psychiatric disorders; major Depression;asthma;anemia; hyperthyroidism;sleep disorders;diabetes and high blood pressure; alcohol abuse;drug abuse; HMG coa reductase inhibitors; beta blockers; calcium channel blockers; statins, levodopa;Sleep disorders The study population of patients with MS who were referred to a neurology clinic and complain fatigue with FSS equal 4 or more than 4 and they have to fill out a consent form. 15 subjects in each of the two groups taking amantadine,coenzymenQ 10 and placebo (total n = 45) for 28 days at baseline and at the end of this term fss they will be check.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013092814792N1**

Registration date: **2013-11-28, 1392/09/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-11-28, 1392/09/07

Registrant information

Name

Arash Bostani

Name of organization / entity

Emam Reza hospital of kermanshah University of

Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1427 6309

Email address

medmehr81@gmail.com

Recruitment status

Recruitment complete

Funding source

Kermanshah Univesity of Medical Science

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of amantadine and coenzymeQ10 on the fatigue of the Multiple Sclerosis patients

Public title

The effect of amantadine and Q10 in fatigue of the Multiple Sclerosis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Informed consent form and questionnaire filling; FSS greater than or equal to 4.0 Exclusion criteria: Use of sedative-hypnotic drugs in the last 2 months;Pregnancy or lactation; Congestive heart failure;kidney or liver disease; psychiatric disorders; major Depression;asthma;anemia; hyperthyroidism;sleep disorders;diabetes and high blood pressure; alcohol

abuse;drug abuse; HMG coa reductase inhibitors; beta blockers; calcium channel blockers; statins, levodopa;Sleep disorders

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

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

Kermanshah University of Medical Science

Street address

Kermanshah University of Medical Science,-Shahid Beheshty boulevard,-kermanshah city,-iran

City

Kermanshah

Postal code

Approval date

2013-04-30, 1392/02/10

Ethics committee reference number

9612

Health conditions studied

1

Description of health condition studied

Fatigue in multiple sclerosis patients

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Fatigue

Timepoint

The beginning and 4 weeks after the end of study

Method of measurement

FSS Questionnaire

Secondary outcomes

1

Description

Drug side effects

Timepoint

Bigenning,during the study,and four weeks after the end of study

Method of measurement

Ask the patients

Intervention groups

1

Description

placebo twice a day for 4 week

Category

Treatment - Drugs

2

Description

coenzyme Q10 60 mg twice a day for 4 weeks

Category

Treatment - Drugs

3

Description

cap Amantadine 100 mg twice a day for 4 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurology clinic of emam Reza hospital

Full name of responsible person

Street address

Neurology clinic,-Emam Reza hospital,-Sorkhe Ije,-Kermanshah,-Iran

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University Of Medical Science

Full name of responsible person

Dr arash bostani

Street address

Kermanshah University of Medical Science,-Shahid beheshty boulevard,-Kermanshah city,-Iran,-Kermanshah

City

Kermanshah

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kermanshah University Of Medical Science

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**

Kermanshah University of Medical Science

Full name of responsible person

Dr Arash Bostani

Position

Assistant professor

Other areas of specialty/work**Street address**

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Web page address

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Contact**Name of organization / entity**

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Dr Arash Bostani

Position

Assistant professor

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Dr Saide Tahmasebi

Position

Resident of neurology

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City

Kermanshah

Postal code**Phone**

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Fax**Email****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