Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Siences
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
Fatige

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 lije,-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

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Person responsible for updating data

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Dr Saide Tahmasebi

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Kermanshah University Of Medical Science,-shahid beheshty boulevard,-Kermanshah-Iran

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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