Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

comparison of Carnitine with placebo for the Treatment of Fatigue in Patients with Multiple Sclerosis in a Randomized Double-blind Clinical Trial

Protocol summary

Summary

In a period of 8 weeks, a randomized, double-blind clinical trial was carried out to compare the effects of carnitine and placebo on improving fatigue symptom in MS patients. Patients with relapsing-remitting MS, with Expanded Disability Status Scale (EDSS) less than 4.0, MS related fatigue with a Fatigue Severity Scale (FSS) >4, who had been receiving interferon β therapy for at least one year, were included. Patients with symptoms of depression, relapse within previous 8 weeks were excluded. Eligible patients were randomly assigned to one of two groups after obtaining written informed consent. one group received 1000mg/d carnitine and one group received placebo. A total of 66 patients were assessed at the beginning of the study and after 8 weeks using Fatigue Severity Scale (FSS).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012092010891N1**
Registration date: **2014-12-23, 1393/10/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-12-23, 1393/10/02

Registrant information

Name

Fereshteh Ashtari

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 913 114 7644

Email address

f_ashtari@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan Neuroscience Research Center, Isfahan University of Medical Sciences

Expected recruitment start date

2011-06-01, 1390/03/11

Expected recruitment end date

2011-07-30, 1390/05/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of Carnitine with placebo for the Treatment of Fatigue in Patients with Multiple Sclerosis in a Randomized Double-blind Clinical Trial

Public title

Carnitine for the Treatment of Fatigue in Multiple Sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: definite relapsing-remitting MS according to McDonald’s criteria؛ age between18 and 50 years; Expanded Disability Status Scale (EDSS) less than 4.0; MS related fatigue with a Fatigue Severity Scale (FSS)>4; receiving interferon β therapy for at least one year Exclusion Criteria: symptoms of depression (Beck Depression Criteria-pc>5); relapse within previous 8

weeks; had received corticosteroids within previous 8 weeks; had received medications affecting MS related fatigue

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **67**

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
Isfahan University of Medical Sciences

Street address
Isfahan, Hezarjrib St

City
Isfahan

Postal code

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
389187

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
decrease of fatigue(FSS)

Timepoint
week 4 and 8

Method of measurement
FSS score

Secondary outcomes

1

Description
drug side effects

Timepoint
4,8 weeks

Method of measurement
recall

Intervention groups

1

Description
intervention group: carnitine 1000mg/d for 8 weeks (tab 500mg, bid)

Category
Treatment - Drugs

2

Description
control: placebo for 8 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Kashani Hospital

Full name of responsible person
fereshte ashtari

Street address
Kashani St., Kashani Hospital, MS clinic

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Isfahan University of Medical Sciences

Full name of responsible person
Payman Adibi

Street address
Hear Jerib st

City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan University of Medical Sciences
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
Isfahan Medical School
Full name of responsible person
Fereshteh Ashtari, Neurologist
Position
Professor
Other areas of specialty/work
Street address
Isfahan, Kashani Hospital
City
Isfahan
Postal code
Phone
+98 31 1235 0094
Fax
Email
f_ashtari@med.mui.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Isfahan Medical School
Full name of responsible person
Fereshteh Ashtari, Neurologist
Position
Professor
Other areas of specialty/work
Street address
Isfahan, Kashani Hospital
City
Isfahan
Postal code
Phone
+98 31 1235 9091
Fax
Email
f_ashtari@med.mui.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Mojtaba Akbari
Position
Epidemioliogist
Other areas of specialty/work
Street address
Hezar Jerib Ave, Isfahan University of Medical Sciences,Medical Faculty
City
Esfahan
Postal code
0098311624977
Phone
+98 31 1624 9773
Fax
Email
akbarim@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