Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Nov 2026

Evaluating the effect of L-carnitine supplement on fatigue severity in patients with multiple sclerosis

Protocol summary

Study aim
determining the effect of L-carnitine supplement on fatigue severity in patients with multiple sclerosis

Design
Clinical trial with control group, with 2 parallel groups, double-blind, with 112 patients in total, 56 patients in each group and randomized. The RALLOC module in Stata software will be used for randomization.

Settings and conduct
Patients in the intervention group will receive 2 grams of L-carnitine daily for 2 months, and patients in the control group will receive a placebo with the same appearance as L-carnitine tablets and the same amount. At the end of this period, FSS and MFIS will be received from all patients again and the effects of L-carnitine will be compared with placebo.In the present clinical trial study, the patient, physician, and researcher will be blind to being placed in drug or placebo groups. The study site will be the Razi Hospital Neurology Clinic.

Participants/Inclusion and exclusion criteria
-Inclusion criteria: Patients with RRMS, MFIS SCORE>38 or FSS>4, EDSS≤3.5 in age range between 18 to 60 years. -Exclusion criteria: Patients suffering from depression, Hypothyroidism, Severe renal impairment with GFR<30 mL/min and patient receiving medicines such as Anti-psychotics, MAO inhibitors, Benzodiazepines, TCAs, Anti-epileptics and Barbiturates.

Intervention groups
The Intervention group will receive L-carnitine tablets 2 grams daily for a period of 2 months. The control group will receive a placebo with the same shape and appearance as the L-carnitine tablets and the same amount for a period of 2 months.

Main outcome variables
-Determination of the effects of L-carnitine supplement in comparison with placebo in improving the fatigue of MS patients based on FSS score -Determining the effects of L-carnitine supplement compared with placebo in improving fatigue in MS patients based on MFIS score.

General information

Reason for update
The expected recruitment end date has been extended for three more months since more time is demanded.

Acronym

IRCT registration information
IRCT registration number: **IRCT20211031052928N1**
Registration date: **2021-12-13, 1400/09/22**
Registration timing: **prospective**

Last update: **2022-12-29, 1401/10/08**
Update count: **1**

Registration date
2021-12-13, 1400/09/22

Registrant information

Name
Sana Savadi Osgouei

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2023-03-21, 1402/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effect of L-carnitine supplement on fatigue severity in patients with multiple sclerosis

Public title
L-carnitine in patients with MS
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with RRMS FSS>4 or MFIS>38 EDSS≤3.5
Exclusion criteria:
EDSS≥4 Depression Hypothyroidism Patients receiving medicines like Antipsychotics, MAOi, Benzodiazepines, TCAs, Anti-seizures and Barbiturates Severe kidney disfunction with GFR<30 ml/min
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **112**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to uniformize the distribution of patients in the drug and placebo groups, a randomized blocking method will be used so that patients are evenly distributed in the study groups. At the end of the study, the relationship between different factors and fatigue in patients will be evaluated using multivariate logistic regression method. In this study, random allocation will be done by block randomization method with fixed size blocks with standard methods. The randomization steps will be as follows: 1- Creating a random sequence: Four random sequences for 4 blocks of 28 will be created using the RALLOC module in STATA software. 2- Allocation concealment Allocation coverage will be done using the method of closed matte envelopes with serial numbering. 3- Execution of allocation: The allocation will be performed by the person in charge of the clinical trial.
Blinding (investigator's opinion)
Double blinded
Blinding description
In the present clinical trial study, the patient, physician, and researcher will be blinded to being placed in drug or placebo groups. The researcher will receive the drug product or placebo with a unique code for each patient. the researcher will receive the medicine or placebo in completely closed and invisible containers inside them and completely similar in appearance. Patients will be divided to four blocks of 28-patients blocks using a random number table in drug or placebo groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Science
Street address
International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Approval date
2021-11-29, 1400/09/08
Ethics committee reference number
IR.TBZMED.REC.1400.900

Health conditions studied

1

Description of health condition studied
Fatigue in patients with Relapsing-remitting MS
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Fatigue
Timepoint
fatigue will be evaluated based on MFIS and FSS score before intervention and 2 months after
Method of measurement
Fatigue severity scale (FSS) and Modified fatigue impact scale (MFIS) Questionnaires

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receiving 2 L-carnitine tabletes (1000 mg tablets made by Karen pharma food and supplements) daily for a period of 2 months.
Category
Treatment - Drugs

2

Description
Control group:receiving placebo in the same shape and amount as L-carnitine tablets received by intervention group for a period of 2 months. The placebo will be produced by Pharmaceuticals Department of Tabriz university of medical science.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz university of medical science
Full name of responsible person
Sana Savadi Osgouei
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
IPD will be available upon other researcher request via email to corresponding author, and following validation of the request.
When the data will become available and for how long
data will be available following study completion and without a time limit .
To whom data/document is available
to verified researchers following evaluation of their requests.
Under which criteria data/document could be used
following receipt of a signed form, and agreement note from publisher.
From where data/document is obtainable
data will be obtainable through publisher.
What processes are involved for a request to access data/document
the researcher should send a request to corresponding author and publisher.
Comments