

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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

Country

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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 tablets (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

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

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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

Sana Savadi Osgouei

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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inquiries

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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