Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

The effect of L-carnitin on EDSS score and Quality of life of MS patients

Protocol summary

Study aim
Evaluating the effect of L-carnitine on Quality of life of MS patients

Design
Clinical trial with randomized controlled trial, parallel group, double blinded, 140 patients. RALLOC module in Stata software will be used for randomization.

Settings and conduct
Patients are randomized in two groups. The intervention group will receive L-carnitine one gr twice a day and the placebo group will receive placebo. At the end of 2 month period, the SF-36 score and EDSS score will be evaluated again. and the effects of L-carnitine will be compared with placebo. We will explain to the patients that their information will be kept private and if they won't like to continue the experiment, they can quit anytime. The informed consent will be filled.The patients disability will be investigated with EDSS score by the investigator.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with RRMS، EDSS≤3.5 and aged between 18 to 60 years. Exclusion criteria: Patients with hypothyroidism, EDSS≥4, GFR<30, allergic to L-carnitine and not interested in participating in the trail.

Intervention groups
The patients will be assigned randomly to the intervention either control group. The intervention group will receive L-Carnitine 1000mg tablets twice a day for a period of 2 months. The control group will receive the placebo with the same appearance and dose for 2 months .

Main outcome variables
Investigation of L-carnitin on Quality of life in MS patients
Investigation of L-carnitin on EDSS score in MS patients

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220417054558N1**
Registration date: **2023-06-08, 1402/03/18**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-08, 1402/03/18**
Update count: **0**

Registration date
2023-06-08, 1402/03/18

Registrant information
Name
Afsoon Pooria
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 41 3383 1907
Email address
pooria.a@tbzmed.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-05-22, 1402/03/01
Expected recruitment end date
2024-02-20, 1402/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of L-carnitin on EDSS score and Quality of life of MS patients

Public title
The effect of L-carnitin on EDSS score and Quality of life of MS patients
Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with RRMS Patients with EDSS ≤ 3.5

Exclusion criteria:

Not interested in accompaniment the trial Patients who have EDSS score equal to or higher than 4 Patients with hypothyroidism Patients with severe renal failure of GFR<30 Who have a history of allergy to L-carnitine

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, permuted blocked randomization method will be used. Patients will be assigned to blocks of 28. A table of random numbers will be used to assign patients to drug or placebo groups. 5 random sequences, for 5 blocks of 28, will be built by RALLOC module in STATA software. Sealed and matte envelopes will be used to conceal the allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

All participants, investigator and physicians will be blinded. Patients who meet the inclusion criteria, will receive sealed and numbered envelopes and will be referred to a person who is responsible for delivering the product. The delivery person who is also blinded will be supposed to open the envelope and give product A or B to the participants.

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 sciences

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

2023-04-17, 1402/01/28

Ethics committee reference number

IR.TBZMED.REC.1402.081

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

The score of Quality of life in SF-36 questionnaire

Timepoint

Measurement of quality of life score after consumption of L-Carnitine for 2 months.

Method of measurement

SF-36 Questionnaire

Secondary outcomes

1

Description

EDSS score

Timepoint

Measurement of EDSS score after consumption of L-carnitine for 2 months.

Method of measurement

EDSS Questionnaire

Intervention groups

1

Description

Intervention group: L-carnitine 1 gr twice a day for two months (made by Karen food and pharma)

Category

Treatment - Drugs

2

Description
Control group: Placebo twice a day for two months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
Afsoon Pooria
Street address
Neurology group office., Imam reza hospital of Tabriz., Daneshgah ave., Golgasht ave,
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2

Recruitment center
Name of recruitment center
Razi hospital
Full name of responsible person
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Neurology department., Razi hospital of Tabriz., Elgoli ave., Next to Shohada hospital,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Parviz Shahabi
Street address
Tabriz, Golgasht st., Tabriz university of medical sciences, Central building No. 2, third floor of the vice chancellor for research and technology
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Web page address
https://researchvice.tbzmed.ac.ir/
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
Afsoon Pooria
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurology
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Person responsible for scientific inquiries

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Email
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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