Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of omega-3 supplementation on serum levels of brain-derived neurotrophic factor, high-sensitivity C-reactive protein, and chronic fatigue in patients with multiple sclerosis

Protocol summary

Study aim

Investigating the effect of omega-3 supplementation on serum levels of brain-derived neurotrophic factor, high-sensitivity C-reactive protein, and chronic fatigue in patients with multiple sclerosis

Design

This double-blind, randomized, phase 2 clinical trial will be conducted on 60 patients with multiple sclerosis (MS), including two intervention (n=30) and control (n=30) groups. The method of random allocation is using a table of random numbers.

Settings and conduct

This double-blind study is conducted at Abadan University of Medical Sciences in collaboration with the Khuzestan MS Association. MS patients who meet the conditions to enter the study are invited to the study by phone. A trained student randomly assigns patients to each of the intervention and control groups. On the first day of the visit, personal information questionnaires, dietary intake of omega-3 fatty acids, chronic fatigue scale, and physical activity are completed. 2 cc of blood is taken from the patient and a supplement or placebo is provided to the patient. At the end of the third month, patients will complete the chronic fatigue questionnaire and IPAQ again, and 2 cc of blood will be taken from the patient after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Age 18-85 years - Diagnosis of MS Exclusion criteria: - Recurrence or treatment with corticosteroids in the last month - Simultaneous treatment with antibiotics and antihypertensive drugs - Pregnancy

Intervention groups

1. Intervention group: recipients of omega-3 fatty acid soft capsules with a dose of 1000 mg/d twice a day for 12 weeks. 2. Control group: recipients of oral soft paraffin capsules as a placebo with a dose of 1000 mg/day twice a day for 12 weeks.

Main outcome variables

Brain-derived neurotrophic factor, and high sensitive C-reactive protein serum levels, Physical activity score, Chronic fatigue scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240604062003N1**
Registration date: **2024-07-28, 1403/05/07**
Registration timing: **retrospective**

Last update: **2024-07-28, 1403/05/07**
Update count: **0**

Registration date

2024-07-28, 1403/05/07

Registrant information

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Mahshid Naghashpour

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-30, 1403/03/10

Expected recruitment end date

2024-06-30, 1403/04/10

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of omega-3 supplementation on serum levels of brain-derived neurotrophic factor, high-sensitivity C-reactive protein, and chronic fatigue in patients with multiple sclerosis

Public title
Effect of omega-3 supplementation on myelination, inflammation, and chronic fatigue in patients with multiple sclerosis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18-85 years MS diagnosis by a neurologist based on McDonald's criteria (98) Under treatment with MS-modifying drugs with a fixed dose from 6 months before enrolling in the study
Exclusion criteria:
Participants in other trials except for the current clinical trial Recurrence or treatment with corticosteroids in the last month- Simultaneous treatment with antibiotics and antihypertensive drugs Other acute or severe diseases except for MS Pregnancy Current or past history of ventricular arrhythmia General health condition that interferes with participation in the study.
Age
From **18 years** old to **85 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization The first step - creating a random sequence (Randomization) In this study, a simple randomization method will be used using a table of random numbers to create a random sequence. To use the table of random numbers, the researcher first predetermines the order of reading the numbers in the table (from above) and then considers even numbers as a default for the intervention group (A) and odd numbers for the control group (B). Then he puts his hand on one of the numbers, moves in one of the predetermined directions, records the numbers, and assigns them to different groups. The second stage - Allocation concealment In this study, opaque sealed and waxed envelopes are used sequentially to hide random allocation (numbered, sealed, opaque envelopes). In this method, after creating a random sequence, based on the research sample size, several envelopes With aluminum wrapping (to obscure the contents of the envelopes), each of the created random sequences is recorded on a card and the cards are placed in the letter envelopes to preserve the random sequence as well. on the surface The outside of the envelopes is numbered in the same order. Finally, the envelopes are sealed and placed inside a box. The envelopes are opened in order and the assigned group of that participant is revealed. An independent medical student (researcher) prepares supplements or supplements with the same color and shape (placebo) as assigned. and puts it in the envelope according to the allocation order. These supplements cannot be distinguished because they contain cans with the same color, shape, and label. The third step - implementing the random allocation process In this study, one of the researchers (faculty member) creates a random sequence, a student who is aware of the study, examines the participants in terms of entry and exit criteria and registers them in the study, and also Another medical student (third party) assigns the participants to groups. The researcher who created the random sequence must be separate from other researchers in the stage of registering the names or allocation of individual participants to reduce possible bias.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is conducted in a double-blind manner. In this way, both the participants and the researchers or the outcome assessors are unaware of the allocation of the study groups. The drugs prepared as placebo are completely similar to the omega-3 supplement in terms of color, appearance of the cans and gelatin capsules, smell, and the method of use that is included on the placebo cans so that blinding can be done at the level of the study participants.
Placebo
Used
Assignment
Parallel
Other design features
Dose not have

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Abadan University of Medical Sciences
Street address
Airport Ave, Abadan university of Medical Sciences, Abadan, Khuzestan, Iran
City

Abadan

Province

Khouzestan

Postal code

6313617202

Approval date

2020-04-11, 1399/01/23

Ethics committee reference number

IR.ABADANUMS.REC.1399.006

Health conditions studied

1

Description of health condition studied

Multiple Sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis (of):NOS brain stem cord disseminated generalized

Primary outcomes

1

Description

Mean of Brain-derived neurotrophic factors serum levels

Timepoint

At the beginning of the study (before the start of the intervention) and 12 weeks after the start of taking the omega-3 supplement

Method of measurement

Measurement of BDNF by ELISA: Blood samples will be collected at the beginning and end of the study from all participants between 9:00 and 12:30 to measure total BDNF levels in the serum and clotted for 1 hour at room temperature and then 1 hour at room temperature. It is placed at 4 degrees Celsius. Then, the serum was separated using a centrifuge at 2000 rpm for 10 minutes at 4°C, aliquoted, and stored at -80°C until use in 0.2 ml tube strips (Sarstedt, Multiply® µStripPro). To measure total BDNF serum level, the ELISA kit manufactured by Zelbio, Germany will be used (99).

2

Description

Mean of high sensitive C-reactive protein serum levels

Timepoint

At the beginning of the study (before the start of the intervention) and 12 weeks after the start of taking the omega-3 supplement

Method of measurement

Measurement of hs-CRP: The obtained blood samples will be used to measure the serum inflammatory factor hs-CRP by the Turbidimetric immunoassay (immunoturbidimetry) method.

Secondary outcomes

1

Description

Measure of physical activity

Timepoint

At the beginning of the study (before the start of the intervention) and 12 weeks after the start of taking the omega-3 supplement

Method of measurement

To evaluate physical activity, the International Physical Activity Questionnaire (IPAQ) is used.

2

Description

Mean of chronic fatigue scale score

Timepoint

At the beginning of the study (before the start of the intervention) and 12 weeks after the start of taking the omega-3 supplement

Method of measurement

Assessment of chronic fatigue scale score: A questionnaire consisting of 10 "physical" items, 10 "cognitive" items, and 20 "social" items is used to measure the extent of chronic fatigue of patients in the last 4 weeks.

Intervention groups

1

Description

Intervention group: recipients of omega-3 fatty acid soft capsules with a dose of 1000 mg/d (Zahravai, Tabriz, Iran) twice a day for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: recipients of oral soft paraffin capsules as a placebo with a dose of 1000 mg/day (Zahravai, Tabriz, Iran) twice a day for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

MS Association of Khuzestan Province

Full name of responsible person

Dr. Nastaran Madjdinasab

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1

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Grant name
Funding from the Research and Technology Vice-Chancellor of Abadan University of Medical Sciences
Grant code / Reference number
1399T-716
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Abadan 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
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Full name of responsible person
Dr. Mahshid Naghashpour
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable