Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Omega-3 supplementation on serum level of interferon-gamma in patients with multiple sclerosis

Protocol summary

Study aim

Comparison of the mean total interferon gamma serum levels between MS patients treated with omega-3 supplements and placebo before and after the intervention by sex, age, BMI, and disease duration

Design

Patients covered by the MS Association of Khuzestan province, Abadan, and Ahvaz branches are included in the study. Patients' sera are collected to measure the level of gamma interferon. The study is conducted as a randomized double-blind clinical trial with parallel groups of 60 patients.

Settings and conduct

Multiple sclerosis is an autoimmune and inflammatory disease. Omega-3 fatty acids are a family of unsaturated fatty acids that are essential for regulating the activities of the human body. Several studies have shown the neuroprotective role of omega-3 fatty acids in various conditions, including neurodegenerative diseases. This study will be conducted at Abadan University of Medical Sciences in collaboration with the Khuzestan MS Association. Blinding will be two-way.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18-85 years, MS diagnosis, All types of MS) - Being treated with MS course-modifying drugs Exclusion criteria: Participants in other trials, Recurrence, or treatment with corticosteroids in the last month, Simultaneous treatment with antibiotics and antihypertensive drugs, Other acute or severe diseases, Pregnancy, ventricular arrhythmia, General health condition that interferes with participation in the study

Intervention groups

Intervention group: Omega-3 fatty acid soft capsules with a dose of 1000 mg per day are received twice a day after lunch and dinner for 12 weeks. Control group: Oral soft paraffin capsule as a placebo with a dose of 1000 mg twice a day after lunch and dinner for 12 weeks.

Main outcome variables

The outcome of this study is the serum interferon-gamma level.

General information

Reason for update

Acronym

MS

IRCT registration information

IRCT registration number: **IRCT20240702062304N1**
Registration date: **2024-07-07, 1403/04/17**
Registration timing: **prospective**

Last update: **2024-07-07, 1403/04/17**
Update count: **0**

Registration date

2024-07-07, 1403/04/17

Registrant information

Name

Sahar Golabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-21, 1403/04/31

Expected recruitment end date

2024-11-20, 1403/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of Omega-3 supplementation on serum level of interferon-gamma in patients with multiple sclerosis

Public title
Effect of Omega-3 supplementation in patients with multiple sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with MS (diagnosis of MS based on McDonald's criteria) Age 18 to 85 years All types of MS (relapsing-remitting and progressive types) Treated with MS course-modifying drugs at a fixed dose for 6 months before study enrollment

Exclusion criteria:
Participants in other trials except the present clinical trial Recurrence or treatment with corticosteroids in the last month Simultaneous treatment with antibiotics and antihypertensive drugs Other acute or severe diseases except MS Pregnancy Current or past history of ventricular arrhythmia A general health condition that interferes with participation in the study

Age
From **18 years** old to **85 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The random allocation of the participants to two intervention and control groups will be done using random allocation software and random numbers generated by the computer.The sequence of random allocation, registration of patients, and their allocation in intervention and control groups will be done by trained students. After meeting the inclusion criteria, participants are randomized to receive omega-3 fatty acid supplementation or placebo by a trained student who distributes omega-3 fatty acid capsules or placebo according to a computer-generated randomization list. Randomization and allocation will be concealed from investigators and patients until the final analysis is completed. To control the effect of indoctrination following the consumption of capsules, a placebo will also be used in the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding will be two-way. In this way, the participants and the researcher will not know about the allocation group. Blinding will be done and followed up during 3 months by asking the participants and all the research staff involved in prescribing and measuring the results regarding being aware of the group allocation.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Abadan University of Medical sciences

Street address
Educational, research and technology deputy of Abadan University of Medical Sciences, in front of Ayatollah Jami Airport, Abadan, Iran

City
Abadan

Province
Khouzestan

Postal code
6313833177

Approval date
2020-04-11, 1399/01/23

Ethics committee reference number
IR.ABADANUMS.REC.1399.011

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
Serum interferon-gamma level

Timepoint
Interferon gamma serum levels will be measured before and after the period of use (3 months) in the drug and placebo groups.

Method of measurement
Using a specialized kit for measuring interferon gamma by ELISA method

Secondary outcomes

1

Description
Serum interferon- gamma level
Timepoint
Before the start of the intervention - day 1 of the study and after the end of the intervention - day 90 of the study
Method of measurement
Using a specialized kit for measuring interferon gamma factor in human serum by ELISA method

Intervention groups

1

Description
Intervention group: They will receive a dose of 1000 mg of omega-3 for three months, two omega-3 softgels daily.
Category
Treatment - Drugs

2

Description
Control group: will receive a dose of 1000 mg of omega-3 placebo for three months, two omega-3 placebo softgels daily.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
Sahar Golabi
Street address
In front of Azad University, Nurse Square, Abadan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Abadan University of Medical Sciences
Full name of responsible person
Hamidreza Zaheri
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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
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
Abadan University of Medical Sciences
Full name of responsible person
Sahar Golabi
Position
Associate Professor of Medical Physiology
Latest degree
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Other areas of specialty/work
Physiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Due to the personal nature of the disease and in order to protect the privacy of the patients as much as possible, there is no plan for publication.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available