# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 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

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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
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In front of Azad University, Nurse Square, Abadan, Iran
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
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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**
Ph.D.
**Other areas of specialty/work**
Physiology
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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