Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of black seed oil supplementation on inflammatory biomarkers, neurological function, and quality of life in Patients with Multiple Sclerosis: A Randomized, Double-Blind, Placebo-Controlled Clinical Trial

Protocol summary

Study aim

تعیین تأثیر مکمل‌یاری با روغن سیاه‌دانه بر شاخص‌های التهابی، استرس اکسیداتیو، شدت بیماری، عملکرد شناختی و حرکتی، خستگی، کیفیت زندگی، استرس، فشار خون، قند خون ناشتا و پروفایل لیپیدی در بیماران مبتلا به مالتیپل اسکلروزیس.

Design

Randomized, double-blind, placebo-controlled trial, two parallel groups, in 60 patients. Stratified block randomization with sealed envelopes.

Settings and conduct

The study is conducted at the Multiple Sclerosis Association in Ahvaz. 60 patients are randomly divided into two groups. Blood samples are collected before and after the intervention. Participants, investigators, and the outcome assessor are blinded.

Participants/Inclusion and exclusion criteria

Patients with Relapsing-Remitting Multiple Sclerosis, age 18 to 65 years, diagnosis confirmed by a neurologist, signing informed consent, no use of anti-inflammatory or antioxidant supplements in the past 3 months, no type 2 diabetes or severe cardiovascular disease, no pregnancy or lactation; exclusion: unwillingness to sign consent, progressive type, age out of range, use of mentioned supplements, diabetes or cardiovascular disease, pregnancy or lactation.

Intervention groups

The intervention group receives 1000 milligrams of black seed oil daily and the control group receives placebo (sunflower oil) for 8 weeks. Both groups continue their standard treatment.

Main outcome variables

Inflammatory markers (CRP, ESR, IL-6, TNF-α, IL-17, TGF-β, Ferritin); oxidative stress markers (MDA, TBARS) and antioxidant markers (SOD, GPx, TAC); disease severity (EDSS); cognitive function (MoCA, SDMT); motor function (T25FW); fatigue severity (FSS); quality of life (MSIS-29); stress level (PSS); lipid profile (Chol, TG, LDL, HDL); fasting blood sugar (FBS); blood pressure.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260918071095N1**
Registration date: **2026-09-24, 1405/07/02**
Registration timing: **registered_while_recruiting**

Last update: **2026-09-24, 1405/07/02**
Update count: **0**

Registration date

2026-09-24, 1405/07/02

Registrant information

Name

Hossein Kameli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3311 4114

Email address

kameli_h@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-28, 1405/04/07

Expected recruitment end date

2026-10-29, 1405/08/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of black seed oil supplementation on inflammatory biomarkers, neurological function, and quality of life in Patients with Multiple Sclerosis: A Randomized, Double-Blind, Placebo-Controlled Clinical Trial

Public title

Effect of Black Seed Oil on Inflammation, Neurological Function, and Quality of Life in Patients with Multiple Sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Signing the informed consent form Definitive diagnosis of Relapsing-Remitting Multiple Sclerosis based on McDonald criteria Confirmation of diagnosis by a neurologist Age between 18 and 65 years No use of other anti-inflammatory or antioxidant supplements in the past 3 months Acceptance of regular consumption of black seed oil supplement during the study No chronic comorbid diseases such as type 2 diabetes and severe cardiovascular diseases No pregnancy or lactation in female participants No history of severe or chronic gastrointestinal problems

Exclusion criteria:

Unwillingness to sign the informed consent form Diagnosis of Primary Progressive or Secondary Progressive Multiple Sclerosis Lack of confirmation of diagnosis by a neurologist Age younger than 18 years or older than 65 years Use of other anti-inflammatory or antioxidant supplements in the past 3 months Non-acceptance of regular consumption of black seed oil supplement during the study Presence of chronic comorbid diseases such as type 2 diabetes Presence of severe cardiovascular diseases Pregnancy or lactation in women History of severe or chronic gastrointestinal problems Presence of acute infection or systemic diseases during the study period Use of new drugs that may affect inflammatory and oxidative stress markers Unwillingness to continue cooperation and voluntary withdrawal

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

This study uses stratified randomization. First, participants are divided into homogeneous groups (strata) based on influential variables including age, gender, and disease severity according to the EDSS scale. Then, within each stratum, a random sequence for allocating individuals to the intervention and control groups is generated using block randomization with blocks of four. The unit of randomization is individual. Randomization tools include statistical software and sealed envelopes. For allocation concealment, the sealed envelope method is used. Accordingly, the random sequence is placed inside opaque, sealed envelopes, and each envelope is opened only at the moment of allocation of the individual to the respective group. This method ensures that investigators and participants remain unaware of the group assignment until the time of allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is designed as a randomized, double-blind clinical trial. In this study, participants and investigators will be unaware of the assigned group (intervention or control). To achieve this, a concealed allocation method using sealed, block-randomized, and coded envelopes will be used. The packages containing black seed oil supplement and placebo are completely identical in shape, color, odor, and weight and are coded by the manufacturer so that neither participants nor investigators can identify their contents. The outcome assessor is also unaware of the participants' group allocation, and assessments are performed by a blinded, fixed assessor. Data analysis will also be performed after the study completion while maintaining group blinding. In case of severe adverse events, if necessary, the code for the respective group will be unblinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd., Ahvaz, Khuzestan, Iran

City

Ahvaz

Province
Khouzestan
Postal code
۶۱۳۵۷۱۵۷۹۴
Approval date
2026-06-27, 1405/04/06
Ethics committee reference number
IR.AJUMS.REC.1405.140

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis+
ICD-10 code
Multiple s
ICD-10 code description
G35

Primary outcomes

1

Description
Glutathione Peroxidase Enzyme Activity in Blood Serum
Timepoint
Measurement of Glutathione Peroxidase Enzyme Activity at Baseline (Before the Intervention) and 8 Weeks After the Start of Black Seed Oil Supplementation
Method of measurement
Measurement of Glutathione Peroxidase Enzyme Activity in Blood Serum Using Karmania Pars Gene Company Kit and Enzyme-Linked Immunosorbent Assay Method

2

Description
Superoxide Dismutase Enzyme Activity in Blood Serum
Timepoint
Measurement of Superoxide Dismutase Enzyme Activity at Baseline (Before the Intervention) and 8 Weeks After the Start of Black Seed Oil Supplementation
Method of measurement
Measurement of Superoxide Dismutase Enzyme Activity in Blood Serum Using Karmania Pars Gene Company Kit and Enzyme-Linked Immunosorbent Assay Method

3

Description
Malondialdehyde Level in Blood Serum
Timepoint
Measurement of Malondialdehyde Level at Baseline (Before the Intervention) and 8 Weeks After the Start of Black Seed Oil Supplementation
Method of measurement
Measurement of Malondialdehyde Level in Blood Serum Using Karmania Pars Gene Company Kit and Enzyme-Linked Immunosorbent Assay Method

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Description
Total Antioxidant Capacity in Blood Serum
Timepoint
Measurement of Total Antioxidant Capacity at Baseline (Before the Intervention) and 8 Weeks After the Start of Black Seed Oil Supplementation
Method of measurement
Measurement of Total Antioxidant Capacity in Blood Serum Using Karmania Pars Gene Company Kit and Enzyme-Linked Immunosorbent Assay Method

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Description
C-Reactive Protein Level in Blood Serum
Timepoint
Measurement of C-Reactive Protein Level at Baseline (Before the Intervention) and 8 Weeks After the Start of Black Seed Oil Supplementation
Method of measurement
Measurement of C-Reactive Protein Level in Blood Serum Using Autoanalyzer

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Description
Erythrocyte Sedimentation Rate
Timepoint
Measurement of Erythrocyte Sedimentation Rate at Baseline (Before the Intervention) and 8 Weeks After the Start of Black Seed Oil Supplementation
Method of measurement
Measurement of Erythrocyte Sedimentation Rate Using Specific Tube and Westergren Technique

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Description
Interleukin 6 Level in Blood Serum
Timepoint
Measurement of Interleukin 6 Level at Baseline (Before the Intervention) and 8 Weeks After the Start of Black Seed Oil Supplementation
Method of measurement
Measurement of Interleukin 6 Level in Blood Serum Using Karmania Pars Gene Company Kit and Enzyme-Linked Immunosorbent Assay Method

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Description
Tumor Necrosis Factor Alpha Level in Blood Serum
Timepoint
Measurement of Tumor Necrosis Factor Alpha Level at Baseline (Before the Intervention) and 8 Weeks After the Start of Black Seed Oil Supplementation
Method of measurement
Measurement of Tumor Necrosis Factor Alpha Level in Blood Serum Using Karmania Pars Gene Company Kit and Enzyme-Linked Immunosorbent Assay Method

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Description
Interleukin 17 Level in Blood Serum
Timepoint
Measurement of Interleukin 17 Level at Baseline (Before the Intervention) and 8 Weeks After the Start of Black Seed Oil Supplementation
Method of measurement
Measurement of Interleukin 17 Level in Blood Serum Using Karmania Pars Gene Company Kit and Enzyme-Linked Immunosorbent Assay Method

10

Description
Transforming Growth Factor Beta Level in Blood Serum
Timepoint
Measurement of Transforming Growth Factor Beta Level at Baseline (Before the Intervention) and 8 Weeks After the Start of Black Seed Oil Supplementation
Method of measurement
Measurement of Transforming Growth Factor Beta Level in Blood Serum Using Karmania Pars Gene Company Kit and Enzyme-Linked Immunosorbent Assay Method

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Description
Ferritin Level in Blood Serum
Timepoint
Measurement of Ferritin Level at Baseline (Before the Intervention) and 8 Weeks After the Start of Black Seed Oil Supplementation
Method of measurement
Measurement of Ferritin Level in Blood Serum Using Karmania Pars Gene Company Kit and Enzyme-Linked Immunosorbent Assay Method

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Description
Multiple Sclerosis Disease Severity Based on Expanded Disability Status Scale
Timepoint
Measurement of Disease Severity at Baseline (Before the Intervention) and 8 Weeks After the Start of Black Seed Oil Supplementation
Method of measurement
Assessment of Disease Severity Using Expanded Disability Status Scale by a Neurologist

13

Description
Cognitive Function Based on Montreal Cognitive Assessment
Timepoint
Measurement of Cognitive Function at Baseline (Before the Intervention) and 8 Weeks After the Start of Black Seed Oil Supplementation
Method of measurement
Assessment of Cognitive Function Using Montreal Cognitive Assessment by a Neurologist

14

Description
Cognitive Function Based on Symbol Digit Modalities Test
Timepoint
Measurement of Cognitive Function at Baseline (Before the Intervention) and 8 Weeks After the Start of Black Seed Oil Supplementation
Method of measurement
Assessment of Cognitive Function Using Symbol Digit Modalities Test by a Neurologist

15

Description
Motor Function Based on Timed 25-Foot Walk Test
Timepoint
Measurement of Motor Function at Baseline (Before the Intervention) and 8 Weeks After the Start of Black Seed Oil Supplementation
Method of measurement
Assessment of Motor Function Using Timed 25-Foot Walk Test

16

Description
Fatigue Severity Based on Fatigue Severity Scale
Timepoint
Measurement of Fatigue Severity at Baseline (Before the Intervention) and 8 Weeks After the Start of Black Seed Oil Supplementation
Method of measurement
Assessment of Fatigue Severity Using Fatigue Severity Scale

17

Description
Quality of Life Based on Multiple Sclerosis Impact Scale
Timepoint
Measurement of Quality of Life at Baseline (Before the Intervention) and 8 Weeks After the Start of Black Seed Oil Supplementation
Method of measurement
Assessment of Quality of Life Using Multiple Sclerosis Impact Scale

18

Description
Perceived Stress Level Based on Perceived Stress Scale
Timepoint
Measurement of Perceived Stress Level at Baseline (Before the Intervention) and 8 Weeks After the Start of Black Seed Oil Supplementation
Method of measurement
Assessment of Perceived Stress Level Using Perceived Stress Scale

19

Description
پروفایل لیپیدی شامل کلسترول تام، تری‌گلیسرید، لیپوپروتئین با چگالی کم و لیپوپروتئین با چگالی بالا در سرم خون
Timepoint
Measurement of Lipid Profile at Baseline (Before the Intervention) and 8 Weeks After the Start of Black Seed Oil Supplementation
Method of measurement
Measurement of Lipid Profile in Blood Serum Using Autoanalyzer

20

Description
قند خون ناشتا در سرم خون
Timepoint
Measurement of Fasting Blood Sugar at Baseline (Before the Intervention) and 8 Weeks After the Start of Black Seed Oil Supplementation
Method of measurement
Measurement of Fasting Blood Sugar in Blood Serum Using Autoanalyzer

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Description
Systolic and Diastolic Blood Pressure
Timepoint
Measurement of Blood Pressure at Baseline (Before the Intervention) and 8 Weeks After the Start of Black Seed Oil Supplementation
Method of measurement
Measurement of Systolic and Diastolic Blood Pressure Using Standard Sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Daily consumption of one 1000 milligram capsule of black seed oil (manufactured by Barij Essence Company) for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: Daily consumption of one 1000 milligram placebo capsule (sunflower oil) that is completely identical in shape, color, odor, and weight to the black seed oil capsule, for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Khuzestan Multiple Sclerosis Association
Full name of responsible person
Seyed Ahmad hossieni
Street address
Room 151, Ground Floor, Rehabilitation Faculty, Opposite MRI Center, Golestan Hospital, Ahvaz, Khuzestan, Iran
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naghmehyazdi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research and Technology, Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Abdollah Rafiei
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Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd., Ahvaz, Khuzestan, Iran
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Email
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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
Deputy of Research and Technology, Ahvaz Jundishapur 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
Ahvaz University of Medical Sciences

Full name of responsible person
Naghmeh Yazdi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Traditional Medicine

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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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Complete study protocol including objectives, design, inclusion and exclusion criteria, intervention methods, and outcomes

When the data will become available and for how long
Access period starts 6 months after publication of the main results and continues for 5 years

To whom data/document is available
Researchers affiliated with academic and scientific institutions

Under which criteria data/document could be used
Only for non-commercial research purposes with citation of the source

From where data/document is obtainable
Naghmeh Yazdi, Ahvaz Jundishapur University of Medical Sciences, Email: naghmeyazdi@yahoo.com

What processes are involved for a request to access data/document

Submission of a written request to the principal investigator's email, review of the request by the research team, approval and sending of documents within a maximum of 2 weeks

Comments