

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Clinical trial of the effect of combined omega-3 and vitamin D supplementation compared with the placebo on clinical and metabolic status in patients with multiple sclerosis

Protocol summary

Study aim

The aim of this study is to determine the effects of combined omega-3 and vitamin D supplementation on clinical and metabolic status in patients with multiple sclerosis.

Design

Parallel double-blind (both patients and researchers) clinical trial.

Settings and conduct

Among patients with multiple sclerosis referred to Beheshti Clinic affiliated to Kashan University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Individuals aged 18-55 years diagnosed with multiple sclerosis will be included in this study.

Exclusion criteria: pregnancy or lactating during the past 6 mo, a history of nephrolithiasis during the previous 5 y, menopause, defined as no regular menstruation, and unwillingness to use appropriate contraception.

Intervention groups

Patients will be assigned into two groups to receive combined vitamin D and omega-3 (n=30) or placebo (n=30).

Main outcome variables

Expanded Disability Status Scale (EDSS) and inflammatory factors (primary outcomes) and markers of insulin metabolism, lipid profile and oxidative stress biomarkers (secondary outcomes)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017090133941N20**
Registration date: **2017-11-16, 1396/08/25**

Registration timing: **retrospective**

Last update: **2019-09-18, 1398/06/27**

Update count: **1**

Registration date

2017-11-16, 1396/08/25

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

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ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2017-10-20, 1396/07/28

Expected recruitment end date

2017-11-05, 1396/08/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of combined omega-3 and vitamin D supplementation compared with the placebo on clinical and metabolic status in patients with multiple

sclerosis

Public title
Effect of combined omega-3 and vitamin D supplementation in treatment of multiple sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with multiple sclerosis Aged 18-55 years Course of disease relapsing-remitting MS (RRMS) EDSS ≤ 4.5
Exclusion criteria:
Pregnancy Lactating during the past 6 month History of nephrolithiasis during the previous 5 y No regular menstruation Menopause Unwillingness to use appropriate contraception

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take either combined omega-3 and vitamin D supplementation (n = 30) or placebo (n = 30). Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)
Double blinded

Blinding description
Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Shahid Beheshti Clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

81151-87159

Approval date

2017-10-19, 1396/07/27

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1396.64

Health conditions studied

1

Description of health condition studied

Multiple Sclerosis

ICD-10 code

G35

ICD-10 code description

Demyelinating disease of the central nervous system

Primary outcomes

1

Description

Expanded Disability Status Scale (EDSS)

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Physical examination by neurologist

2

Description

Hs-CRP

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

3

Description

Nitric oxide

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

Secondary outcomes

1

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

2

Description

Glutathione

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

3

Description

Total antioxidant capacity

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

4

Description

Insulin

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

5

Description

Insulin resistance

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Calculation using HOMA formula

6

Description

Total cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

7

Description

Triglycerides

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

8

Description

HDL

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

9

Description

25-hydroxyvitamin D

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

10

Description

Fasting plasma glucose

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

11

Description

LDL-cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

Intervention groups

1

Description

Intervention group: 2000 mg omega-3 daily (NutMega, Australia) and 50000 IU vitamin D every 2 weeks (Zahravi, Tabriz, Iran), for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo capsule (Barij Essence, Kashan, Iran), for 12 weeks orally.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti Clinic

Full name of responsible person

Ebrahim Kouchak

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Ghotbe Ravandi Boulevard, Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

Street address

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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

Kashan 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

Person responsible for general inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

Ph.D of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Zatollah Asemi

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Fax**Email**

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Web page address**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

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