Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Mohammadreza Sharif

Name of organization / entity

Country
Iran (Islamic Republic of)

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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 previous5 y No regular menstruation Menopause Unwillingnessto 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
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Kashan
Province
Isfehan
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

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Clinic
Full name of responsible person
Ebrahim Kouchak
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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
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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
Academic

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
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Person responsible for updating data

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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
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