Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Clinical trial of the effect of omega-3 plus vitamin E supplementation compared with the placebo on disease severity and metabolic profiles in patients with Parkinson's

Protocol summary

Study aim
The aim of this study is to determine the effects of omega-3 supplementation on disease severity and metabolic profiles in patients with Parkinson's.

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

Settings and conduct
patients with Parkinson's of eligible and referred to Shahid Beheshti Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria
Patients with Parkinson's and aged 50 to 80 years will be included in this study. Exclusion criteria are patients who were already taking omega-3 and/or vitamin E, had depression and had severe psychosis.

Intervention groups
Patients will be assigned to receive either omega-3 plus vitamin E supplements (intervention group: n=30) and placebo (control group: n=30).

Main outcome variables
Fasting blood glucose, insulin resistance, insulin, inflammatory factors, oxidative stress and disease severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT201604035623N73**
Registration date: **2016-04-07, 1395/01/19**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-15, 1398/06/24**
Update count: **1**

Registration date
2016-04-07, 1395/01/19

Registrant information

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Zatollah Asemi

Name of organization / entity
Kashan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source
Kashan University of Medical Sciences

Expected recruitment start date
2016-03-10, 1394/12/20

Expected recruitment end date
2016-04-10, 1395/01/22

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of omega-3 plus vitamin E supplementation compared with the placebo on disease severity and metabolic profiles in patients with Parkinson's

Public title
Effect of supplementation in treatment of patients with Parkinson's

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with Parkinson's Aged 50 to 80 years
Exclusion criteria:
Patients who were already taking omega-3 and/or vitamin E Patients who had depression Patients who had severe psychosis.
Age
From **50 years** old to **80 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 balanced block randomization, subjects will be randomly divided into two groups to take either omega-3 plus vitamin E 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
Isfehan
Postal code
81151-87159
Approval date
2016-03-09, 1394/12/19
Ethics committee reference number
IR.Kaums.REC.1394.141

Health conditions studied

1

Description of health condition studied
Parkinson's disease
ICD-10 code
G31
ICD-10 code description
Other degenerative diseases of nervous system, not elsewhere classified

Primary outcomes

1

Description
High-sensitivity C-reactive protein
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

2

Description
Unified Parkinson's Disease Rating Stage (UPDRS)
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Physical Examination by Neurologist

Secondary outcomes

1

Description
Triglycerides
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

2

Description
HDL-cholesterol
Timepoint
At the beginning of the study and after 12 weeks of

intervention

Method of measurement

Enzymatic kit

3

Description

Total cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

4

Description

Insulin

Timepoint

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

Method of measurement

Elisa kit

5

Description

Fasting plasma glucose

Timepoint

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

Method of measurement

Enzymatic kit

6

Description

LDL-cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

7

Description

Insulin resistance

Timepoint

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

Method of measurement

Calculation using HOMA formula

Intervention groups

1

Description

Intervention group: Omega-3 fatty acid plus vitamin E capsule, 1000 mg omega-3 fatty acid plus 400 IU vitamin E, daily for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo, daily, for 12 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Clinic

Full name of responsible person

Reza Daneshvar

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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

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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

Nutritionist

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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