Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Oct 2026

Clinical trial of the effect of omega-3 plus vitamin E supplementation compared with the placebo on levels of gene expression related with glycemic control, lipid and inflammatory factors in patients with Parkinson's

Protocol summary

Study aim
The aim of this study is to determine the effects of omega-3 plus vitamin E supplementation on levels of gene expression related with glycemic control, lipid and inflammatory factors in in patients with Parkinson's.

Design
This study is a parallel double-blind (both patients and researchers) randomized controlled clinical trial.

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

Participants/Inclusion and exclusion criteria
Inclusion criteria is PD patients aged 50–80 years old. Exclusion criteria are subjects who were already taking omega-3 and/or vitamin E, taking DDP4 inhibitors, statins and anti-inflammatory drugs, have depression and have severe psychosis.

Intervention groups
Patients will be assigned to receive either omega-3 plus vitamin E (n=20) or placebo (n=20). Omega-3 plus vitamin E and placebos capsules are similar in shape and size.

Main outcome variables
Fasting blood samples will be taken at baseline and 12 weeks after the intervention. Levels of gene expression related with glycemic control, lipid and inflammatory factors will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT2017061234497N1**
Registration date: **2017-06-20, 1396/03/30**
Registration timing: **retrospective**

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

Registration date
2017-06-20, 1396/03/30

Registrant information
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Recruitment status
Recruitment complete

Funding source
Kashan University of Medical Sciences

Expected recruitment start date
2017-04-20, 1396/01/31

Expected recruitment end date
2017-04-30, 1396/02/10

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 levels of gene expression related with glycemic control, lipid and inflammatory factors in patients with Parkinson's

Public title
Effect of omega-3 plus vitamin E 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:
Subjects who were already taking omega-3 and/or vitamin E Subjects who were taking DDP4 inhibitors, statins and anti-inflammatory drugs Subjects who had depression and 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: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
At study baseline, after balance randomization, subjects will be randomly divided into two groups to take either vitamin E plus omega-3 supplements (n = 20) or placebo (n = 20). 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
8715981151
Approval date
2017-04-19, 1396/01/30
Ethics committee reference number
IR.Kaums.REC.1396.3

Health conditions studied

1

Description of health condition studied
Parkinson disease
ICD-10 code
G20
ICD-10 code description
Parkinson disease

Primary outcomes

1

Description
Tumor necrosis factor alpha
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

2

Description
Interleukin-1
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

3

Description
Interleukin-8
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

Secondary outcomes

1

Description
Peroxisome proliferator–activated receptor γ (PPARγ)
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

2

Description
Low Density Lipoprotein Receptor (LDLR)
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

Intervention groups

1

Description
Control group: Placebo, daily, for 12 weeks orally.
Category
Treatment - Drugs

2

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

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
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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
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Zatollah Asemi
Position
PhD of Nutrition
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Omid Reza Tamtaji

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MSc student of medical physiology

Latest degree

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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