

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Aug 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 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

Name

Omid Reza Tamtaji

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5562 1157

Email address

tamtaji-or@kaums.ac.ir

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

Isfahan

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 (PPAR γ)

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

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 31 5554 0026

Email

redaneshvar@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 31 5554 2999

Email

research@kaums.ac.ir

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

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 31 5546 3378

Fax

Email

asemi_z@kaums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

PhD of Nutrition

Latest degree

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Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 31 5546 3378

Fax

Email

asemi_z@kaums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Omid Reza Tamtaji

Position

MSc student of medical physiology

Latest degree

Master

Other areas of specialty/work

Physiology

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 31 5562 1157

Fax

Email

tamtaji_or@yahoo.com

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