

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Effect of omega 3 fatty acids supplement on inflammatory factor (IL-1 β , IL-6, TNF- α , IL-10) and lipid profile of prakinson disease.

Protocol summary

Study aim

1- Determination and comparison of the effect of omega-3 fatty acids and placebo on inflammatory factors (TNF- α , IL-1 β and IL-6) and anti-inflammatory agent (IL-10) in Parkinson's patients. 2- Determination and comparison of the effects of omega-3 fatty acids and placebo on lipid profiles (HDL, LDL, and TG) in Parkinson's patients. 3- Determination and comparison of the effect of omega-3 fatty acids on body mass index and body fat percentage in patients with Parkinson's disease.

Design

Clinical trial with community-based and pragmatic control group, with parallel, double-blind, randomized,

Settings and conduct

Patients will be selected from the Neurology Clinic of Imam Reza Hospital. Diagnosis is a neurologist's opinion. The goals and method of the study will be explained to the patients and, after obtaining written informed consent, all samples fill out the demographic information form. They are not asked to change their lifestyle during the course of the study, and continue their daily habits and exercise and previous diet. Each patient will be taken from the right arm in the morning after a 12-hour fasting, centrifuge, and stored at -80 ° C until the analysis is performed. The body composition of the patients will be measured by BIA. Receipt of the data was done by a questionnaire and the MNA questionnaire. The data will be analyzed in terms of energy intake and fatty acid by N4 software. Physical activity evaluation questionnaire (RAPA) will be used to assess the physical activity of patients

Participants/Inclusion and exclusion criteria

44 patients aged 50-70 who meet the criteria for entry and exit criteria, withdrawal criteria: unwillingness to cooperate, patients who had already taken Omega-3 (6 months ago), patients with depression or Psychosis, or other inflammatory disease, patients who can not use supplementation due to digestive problems or allergic

reactions. People who smoke and drink alcohol. Entry criteria: Those with a neurologist who have Parkinson's diagnosis (except for patients with stage 4 and 5 disease) and aged 50-70 years, do not use aspirin or anticoagulant, or statin

Intervention groups

Twenty-two individuals in the intervention group (including two daily omega-3 capsules of EPA: 180mg and DHA of 120mg taken from the Zahravi Pharmaceuticals Company) and 22 patients in the placebo group (two capsules per day, the combination of which Of soybean oil and will be supplied by Zahravi Pharmaceutical Company).

Main outcome variables

Supplementation of omega-3 fatty acids on serum inflammatory factors (TNF- α , IL-1 β and IL-6) and anti-inflammatory agent (IL-10); lipid levels (HDL, LDL and TG); body mass index and percentage The fat affects patients with Parkinson's disease.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100123003140N21**

Registration date: **2018-05-05, 1397/02/15**

Registration timing: **retrospective**

Last update: **2018-05-05, 1397/02/15**

Update count: **0**

Registration date

2018-05-05, 1397/02/15

Registrant information

Name

Bahram Pourghassem Gargari

Name of organization / entity

Health and Nutrition Faculty, Tabriz University of medical sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-04-18, 1396/01/29

Expected recruitment end date
2017-06-19, 1396/03/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of omega 3 fatty acids supplement on inflammatory factor (IL-1 β , IL-6, TNF- α , IL-10) and lipid profile of prakinson disease.

Public title
Effect of omega 3 in Parkinson disease.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Those who have Parkinson's diagnosis by a neurologist
Those aged 50-70 People who do not use aspirin or another anticoagulant, or statin
Exclusion criteria:
Unwillingness to cooperate Patients who already took Omega-3 (6 months ago) Patients who have depression or psychosis or have another inflammatory disease
Patients who are unable to take supplementation due to digestive problems or allergic reactions Patients who smoke and drink alcohol

Age
From **50 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, participants randomly divided into omega-3 and placebo groups, and patients are unaware of being given placebo or omega-3. The doctor is unaware of which omega-3 patients and which placebo are receiving, and the investigator who is responsible for collecting data and analyzing the data is unaware of which patients received placebo and which omega-3s

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشکده تغذیه و علوم غذایی تبریز

Street address

تبریز، خیابان گلگشت ، دانشگاه علوم پزشکی تبریز ، ساختمان مرکزی شماره 2

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Province

East Azarbaijan

Postal code

5166614711

Approval date

2018-03-11, 1396/12/20

Ethics committee reference number

IR.TBZMED.REC.1396.1244

Health conditions studied

1

Description of health condition studied

parkinson

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Serum levels of IL-1B

Timepoint

The beginning and the end of the study

Method of measurement

ELISA KIT

2

Description

Serum levels of IL-6

Timepoint

The beginning and the end of the study

Method of measurement

ELISA KIT

3

Description

Serum levels of TNF-a

Timepoint

The beginning and the end of the study

Method of measurement

ELISA KIT

4

Description

Serum levels of IL-10

Timepoint

The beginning and the end of the study

Method of measurement

ELISA KIT

5

Description

Serum levels of TG

Timepoint

The beginning and the end of the study

Method of measurement

LBL KIT

6

Description

Serum levels of HDL

Timepoint

The beginning and the end of the study

Method of measurement

LBL KIT

7

Description

Serum levels of LDL

Timepoint

The beginning and the end of the study

Method of measurement

By the formula

Secondary outcomes

1

Description

Check for food

Timepoint

At first and during the study

Method of measurement

A 24-hour recall questionnaire and MNA questionnaire
MNA

2

Description

Physical activity review

Timepoint

At the beginig of the study

Method of measurement

RAPA questionnaire

3

Description

Anthropometric Indicators

Timepoint

The beginning and the end of the study

Method of measurement

Impedance bi-electric system

4

Description

BMI

Timepoint

The beginning and the end of the study

Method of measurement

By the formula

5

Description

Serum Alb level

Timepoint

Beginning of study

Method of measurement

Enzymatic

Intervention groups

1

Description

Intervention group: Twenty-two people in the intervention group (including daily two capsules of omega-3 capsules with an EPA of 180mg and DHA of 120mg from the Zahravi Pharmaceuticals Company)

Category

Treatment - Drugs

2

Description

Control group: Twenty-two people in the placebo group (two capsules each day, in combination with soy oil, from Zahrawi Pharmaceuticals Company) will be placed

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

درمانگاه نورولوژی بیمارستان امام رضا

Full name of responsible person

دکتر سمانه حسینی

Street address

East Azarbaijan - Tabriz - Next to the University -
Imam Reza Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Bahram Pourghasem Gargari

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Golghast St. - Attar Neyshaburi St. - Faculty of
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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Bahram Pourghasem Gargari

Position

Faculty Member of Faculty of Nutrition and Food
Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Publish primary and raw results of samples

When the data will become available and for how long

Then finish and publish the draft articles

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

With the permission of the researcher of the project and the sponsor of the project, the Nutrition Research Center and the Research Deputy of the University-

From where data/document is obtainable

Research Center for Nutrition Researchers

What processes are involved for a request to access data/document

In-person attendance and obtaining relevant permissions
_ Phone call

Comments