Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of omega 3 fatty acids supplement on inflamatory factor (IL-1β, 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-1β 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-1β 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 inflamatory factor (IL-1β, 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
City
تبریز
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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dr.hosseini.neurologist@gmail.com

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 Nutrition and Food Sciences

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pourghassemb@tbzmed.ac.ir

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

Contact

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Person responsible for updating data

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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