

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Effect of omega 3 fatty acids supplement on inflammatory factor ( IL-1 $\beta$ , IL-6, TNF- $\alpha$ , IL-10) and lipid profile of Parkinson disease.

#### Protocol summary

##### Study aim

1- Determination and comparison of the effect of omega-3 fatty acids and placebo on inflammatory factors (TNF- $\alpha$ , IL-1 $\beta$  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- $\alpha$ , IL-1 $\beta$  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

**Country**

Iran (Islamic Republic of)

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+98 41 1435 7580

**Email address**

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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 $\beta$ , IL-6, TNF- $\alpha$ , 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**

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**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

**Street address**

Golghast St. - Attar Neyshaburi St. - Faculty of  
Nutrition and Food Sciences

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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

### 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**