

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The assessment of the effect of omega 3 fatty acids supplementation on serum Irisin, BDNF (Brain Derived Neurotrophic Factor) and Myonectin in Patients with diabetes type 2 disease

Protocol summary

Summary

This study is a clinical trial to evaluate the effect of supplementation omega-3 fatty acid on serum levels of Irisin, Myonectin and BDNF on 44 patients with type 2 diabetes in Iran Diabetes Center will be conducted on a voluntary basis this double blind clinical trial is conducted to evaluate the effects of omega 3 fatty acids supplementation on serum levels of Irisin, Myonectin and BDNF in 44 volunteer type 2 diabetic patients of Iran Diabetes Center. Participants divided in two groups of omega 3 fatty acids and placebo recipients based on Permuted Block Randomization. . In 10 weeks duration of this intervention patients will receive omega-3 supplements at a dose of 3750 mg per day (1250 mg per capsule contains omega 3 fatty acids (EPA = 600mg, DHA = 300 mg) and placebo capsules (edible paraffin) at a dose of 3750 mg per day. Thus, each person in the first group receives daily 3 omega 3 fatty acids capsules. In the second group patients received daily 3 placebo capsules contain edible paraffin which are all in the same shape and usage of omega 3 capsules. . Anthropometric measurements and blood pressure will be recorded before and after the intervention. Also, the 24 hours food recalls are be collected and analyzed by the NUT4 software. At the beginning and end of the study 10 ml of patients' blood sample is used to assess the serum concentrations of BDNF, Irisin and Myonectin with ELISA method. Data will be analyzed with Spss version 20.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061922769N3**
Registration date: **2015-08-16, 1394/05/25**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-08-16, 1394/05/25

Registrant information

Name

Mohammad Hassan Javanbakht

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8891 4462

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mhjavan@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

School of Nutritional Sciences & Dietetics, Tehran University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The assessment of the effect of omega 3 fatty acids supplementation on serum Irisin, BDNF (Brain Derived Neurotrophic Factor) and Myonectin in Patients with diabetes type 2 disease

Public title

The effects of Omega 3 fatty acid supplements on treatment of type 2 diabetes complications

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diabetics men and women aged 30-65 years old, ; BMI in the range of 35-25 BMI ranged 25-35; the desire to maintain weight during the study weight maintenance tendency during the study; the tendency to maintain normal activities during the current life style tendency to keep current life style and activities during the study; willingness to cooperate in the project
Exclusion criteria: changing on the dose or types of diabetes medications; inflammatory disease given; unwillingness to continue the cooperation; taking ten percent supplement non using ten or more percent of the supplements; any allergic reactions to omega-3 components

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Sixth Floor, Central Department of University, Ghods St., Keshavarz Blvd.

City

Tehran

Postal code**Approval date**

2010-06-14, 1389/03/24

Ethics committee reference number

IR.tums.REC.1394.36

Health conditions studied**1****Description of health condition studied**

Diabetes type 2

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes**1****Description**

Irisin

Timepoint

The beginning and end of the study (before and after intervention)

Method of measurement

ELISA

2**Description**

Myonectin

Timepoint

The beginning and end of the study (before and after intervention)

Method of measurement

ELISA

3**Description**

BDNF(Brain Derived Neurotrophic Factor)

Timepoint

The beginning and end of the study (before and after intervention)

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: omega-3 polyunsaturated fatty acid supplements at a dose of 3750 mg per day (1250 mg per capsule of omega-3 polyunsaturated fatty acid is containing (EPA = 600mg, DHA = 300 mg).)

Category

Treatment - Drugs

2

Description

Control group: placebo or (paraffin oral) at a dose of 3750 mg per day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taban health clinics and Diabetes and Diabetes Research Center

Full name of responsible person

Dr.Mohammad Hasan Javanbakht

Street address

Taban health clinics and Diabetes, No. 100, The northern Derakhti Blvd., Western Dadman Avenue, Shahrake Gharb / Diabetes and Metabolism specialty and subspecialty clinics, Western deadlock Hayat, 17 Shahrivar street, Amirabad street.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Masud Yunesian

Street address

Sixth Floor, Central Department of University, Ghods St., Keshavarz Blvd.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Nutritional Sciences & Dietetics, Tehran University of Medical Sciences

Full name of responsible person

Mohammad Hasan Javanbakht

Position

PHD Nutrition

Other areas of specialty/work

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Position

PHD Nutrition/Assistant Professor and Faculty member of School of Nutritional Sciences & Dietetics

Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*