

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of effects of ecosapentaenoic acid and docosahexaenoic acid on blood glucose, fat mass, MDA and C-reactive protein in patients with type 2 diabetes

Protocol summary

Summary

1- Objectives: Previous studies have shown that omega-3 fatty acids may reduce inflammation, oxidative stress, and fat mass in patients with type 2 diabetes, but the results are inconclusive, due, in part, to type of omega-3 fatty acids used. The aim of this study is to compare the effects of pure ecosapentaenoic and docosahexaenoic acids, the two major omega-3 fatty acids, on fat mass, oxidative stress, inflammation and blood sugar in patients with type 2 diabetes. 2- Design: double-blind placebo controlled trial 3- Setting and conduct: Sixty patients with type 2 diabetes will be referred from Institute of Endocrinology and Metabolism, Firouzgar Hospital, Tehran University of Medical Sciences. They will be randomly allocated to receive daily either 1 gram ecosapentaenoic or 1 gram docosahexaenoic acids, or a placebo for 12 weeks. Ten milliliters of fasting blood will be taken at baseline and at the end of the intervention. Serum malondialdehyde, C-reactive protein, fasting blood sugar and fat mass will be measured at baseline and after intervention. 4- Participants: 35-65 year-old patients with type 2 diabetes who are overweight and use oral hypoglycemic agent, Exclusion criteria: treatment with insulin; taking fish oil supplements or NSAIDs during the last 3 months before intervention; taking fish more than once a week; having cardiovascular, liver, kidney disease; smoking; weight changes more than three kilograms during three months before intervention; change in type or dose of oral hypoglycemic agent for at least two weeks prior to entry or during intervention; 5- Intervention: 1 gram ecosapentaenoic or docosahexaenoic acid daily , or placebo (canola oil) for 12 weeks 6- Main outcome measures variables: Serum malondialdehyde, C-reactive protein, fasting blood sugar and fat mass

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812102394N4**

Registration date: **2011-06-06, 1390/03/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-06, 1390/03/16

Registrant information

Name

Shima Jazayeri

Name of organization / entity

Iran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2010-06-01, 1389/03/11

Expected recruitment end date

2010-12-01, 1389/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effects of ecosapentaenoic acid and docosahexaenoic acid on blood glucose, fat mass, MDA and C-reactive protein in patients with type 2 diabetes

Public title

Comparison of effects of EPA and DHA in patients with type 2 diabetes

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: 1- Age: 35-65years; 2- Willing to participate; 3- Having diabetes type 2 for at least five years prior to entry; 4- Blood sugar control with biguanide and sulfonylurea drugs for at least of one year prior to entry; 5- Normal blood pressure and lipid profile; 6- BMI : 20-35 kg/m²; Exclusion criteria: 1- Treatment with insulin; 2- Taking fish oil supplements or NSAIDs during the last 3 months before intervention; 3- Taking fish more than once a week; 4- Having cardiovascular, liver, kidney disease; 5- Smoking; 6- Weight changes more than three kilograms during three months before intervention; 7- Change in type or dose of oral hypoglycemic agent for at least two weeks prior to entry or during intervention;

Age

From **35 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd, Tehran, Iran.

City

Tehran

Postal code**Approval date**

2008-11-21, 1387/09/01

Ethics committee reference number

2399

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

Diabetes Mellitus 2

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

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

Fasting blood sugar

Timepoint

at baseline, after 12 weeks

Method of measurement

enzymatic colorimetric

2**Description**

fat mass

Timepoint

at baseline, after 12 weeks

Method of measurement

BIA

3**Description**

malondialdehyde

Timepoint

at baseline, after 12 weeks

Method of measurement

ELISA

4**Description**

C-reactive protein

Timepoint

at baseline, after 12 weeks

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups

1

Description

icosapentaenoic acid: 1000 mg daily (four 250 mg soft gels) 2 times a day (at lunch time and dinner time) for 12 weeks

Category

Treatment - Other

2

Description

docosahexaenoic acid: 1000 mg daily (four 250 mg soft gels) 2 times a day (at lunch time and dinner time) for 12 weeks

Category

Treatment - Other

3

Description

Placebo : canola oil 1000 mg daily (four 250 mg soft gels) 2 times a day (at lunch time and dinner time) for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Institute of Endocrinology and Metabolism, Firouzgar Hospital

Full name of responsible person

Dr. Heidari

Street address

City

Teharn

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd, Tehran, Iran

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shima Jazayeri

Position

Assistant Professor, MD, PhD

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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