

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of DHA supplement on PPAR γ - LXR α - ABCA1 pathway in PPAR γ 2 Pro12Ala genetic variants in type 2 diabetes

Protocol summary

Summary

60 Type 2 diabetic willing to participate in the study consideration of inclusion and exclusion criteria will be invited in this study. The Pro12Ala polymorphism of the PPAR γ 2 gene will be detected by the RFLP method. Homozygote individual for Pro allele (PPAR γ 2 Pro12Pro) and recessive allele (Pro12Ala or Ala12Ala) will be identified. Then matching will be done for BMI, age and sex between control and intervention groups. The following groups will be studied(15 patients in each group): - Ala12Ala or Pro12Ala genotype who will received DHA supplement - Ala12Ala or Pro12Ala genotype who will received placebo - Pro12Pro genotype who will received DHA supplement - Pro12Pro genotype who will received placebo each patient will intake 2 gram DHA (Decosahexanoic Acid) or sunflower oil as placebo for 12 weeks. In the start of study patient learn about food record and three-day food record will be done in the first and end week of intervention by patients. physical activity will be assessed by valued physical activity questionnaire. Experiments: Before and after of intervention anthropometric measures, lipid profile, fasting blood sugar, Insulin, gene expression of LXR and ABCA1 and adiponectine concentration will be measured. Analysis: food intake and biochemistry and gene expression information will be analysis by statistical software at the end of study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013071914013N1**
Registration date: **2013-08-23, 1392/06/01**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-08-23, 1392/06/01

Registrant information

Name

Anahita Mansoori

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences, Endocrinology and Metabolism Research Institute of Tehran University

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2013-09-21, 1392/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of DHA supplement on PPAR γ - LXR α - ABCA1 pathway in PPAR γ 2 Pro12Ala genetic variants in type 2 diabetes

Public title

The effect of DHA supplement on lipid metabolism in diabetic patient

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Type 2 diabetic willing to participate in the study; BMI (kg/m²) between 18.5 to 35; Age from 30 to 60 year
Exclusion criteria: Insulin therapy; Thiazolidinediones therapy; Liver, kidney, coagulation and thyroid disorders; Anticoagulation, anti-inflammation and lipid lowering drug consumption; History of Allergic reaction to fish or fish oil; Daily consumption of fish or w3 supplement; Supplementation with vitamin A, D and B6

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

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

Tehran University of Medical Sciences

Street address

Nutrition and dietetics school, Tehran University of Medical Sciences, 16 Azar Ave, Enghelab Sq, Tehran

City

Tehran

Postal code

Approval date

2013-07-17, 1392/04/26

Ethics committee reference number

92-01-16-20454-89521

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

TG

Timepoint

before and after of intervention

Method of measurement

Enzymatic kit

2

Description

HDL.c

Timepoint

before and after of intervention

Method of measurement

Enzymatic kit

3

Description

LDL.c

Timepoint

before and after of intervention

Method of measurement

Enzymatic Kit

4

Description

Chol

Timepoint

before and after of intervention

Method of measurement

Enzymatic kit

5

Description

ABCA1 gene expression

Timepoint

before and after of intervention

Method of measurement

Real time PCR

6

Description

LXRa gene expression

Timepoint

before and after of intervention

Method of measurement

Real time PCR

Secondary outcomes

1

Description

waist circumference

Timepoint

before and after of interention

Method of measurement

tape meter

2

Description

weight

Timepoint

before and after of intervention

Method of measurement

digital scale

3

Description

BMI

Timepoint

before and after of intervention

Method of measurement

It is calculated by dividing weight(Kg) by height squar(m)

4

Description

body fat percent

Timepoint

before and after of intervention

Method of measurement

BIA

5

Description

fasting blood sugar

Timepoint

before and after of sintervention

Method of measurement

Enzymatic Kit

6

Description

Insulin

Timepoint

before and after of study

Method of measurement

Radioimmunoassy kit(RIA)

7

Description

Adiponectine

Timepoint

before and after of intervention

Method of measurement

ELISA kit

Intervention groups

1

Description

Ala12Ala or Pro12Ala genotype who will received DHA supplement: DHA supplement in shape of soft gel, 2 gram per day for 12 weeks, twice a day with main meal

Category

Treatment - Other

2

Description

Ala12Ala or Pro12Ala genotype who will received placebo : sunflower oil as placebo in shape of soft gel, 2 gram per day for 12 weeks, twice a day with main meal

Category

Placebo

3

Description

Pro12Pro genotype who will received DHA supplement: DHA supplement in shape of soft gel, 2 gram per day for 12 weeks, twice a day with main meal

Category

Treatment - Other

4

Description

Pro12Pro genotype who will received placebo: sunflower oil as placebo in shape of soft gel, 2 gram per day for 12 weeks, twice a day with main meal

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gabric diabetic education association

Full name of responsible person

Mr. Hormoz Kikhan-zadeh

Street address

Gabric diabetic education association- No4- 16th Ave-vozara Ave- Arzhantin Sq- Tehran

City

Tehran

2

Recruitment center

Name of recruitment center

Diabetic Clinic of Endocrinology and Metabolism
Research Institute of Tehran University

Full name of responsible person

Dr Ensieh Nasli

Street address

Diabetic Clinic ofEndocrinology and Metabolism

Research Institute of Tehran University- Kargare'
shomali Ave- Tehran- post code 1411715911

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Akbar Fotouhi

Street address
Research Center of Tehran University of Medical
Sciences

City
Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source
Tehran University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity
Endocrinology and Metabolism Research Institute

Full name of responsible person
Dr.Fariba Koohdani

Street address
Nutrition and dietetics school, Tehran University of
Medical Sciences, 16 Azar Ave, Enghelab Sq, Tehran

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source
Endocrinology and Metabolism Research Institute

Proportion provided by this source

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

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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