Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of DHA supplement on PPARγ- LXRα- ABCA1 pathway in PPARγ2 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 PPARγ2 gene will be detected by the RFLP method. Homozygote individual for Pro allele (PPARγ2 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
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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 PPARγ- LXRα- ABCA1 pathway in PPARγ2 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, ant-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
Enymatic kit

3

Description
LDL.c

Timepoint
before and after of itervention

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

City

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

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Anahita Mansoori

Position

PhD student

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