

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### The effect of DHA supplement on PPAR $\gamma$ - LXR $\alpha$ - ABCA1 pathway in PPAR $\gamma$ 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 $\gamma$ 2 gene will be detected by the RFLP method. Homozygote individual for Pro allele ( PPAR $\gamma$ 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)

###### Phone

+98 21 6691 1514

###### Email address

a-mansoori@razi.tums.ac.ir

##### 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 $\gamma$ - LXR $\alpha$ - ABCA1 pathway in PPAR $\gamma$ 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/m<sup>2</sup>) 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

**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**  
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**Full name of responsible person**  
Anahita Mansoori

**Position**  
PhD student

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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Associate professor

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## Person responsible for updating data

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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*