

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of DHA supplementation on factors influencing vascular thickness and intima-media smooth muscle proliferation in patients with type 2 diabetes mellitus

Protocol summary

Summary

1) Objectives: Studying the effect of Docosahexaenoic acid on effective factors of vascular thickness and function in diabetic patients. 2) Design: 72 T2DM patients will be evaluated for inclusion criteria and submitters will be divided in 2 age, sex, BMI matched groups (n=36) and will be randomized for intervention. 3) Setting and conduct: blood samples will be collected in starting and end of study and biochemical and anthropometric measurements will be conducted. Weight, height, waist circumference, hip circumference will be measured according to standard methods and obesity and central obesity indices will be calculated. Lipid profile, Fasting Blood Sugar, fasting insulin will be measured according to standard methods and serum LDL cholesterol level and insulin resistance will calculate using equations. We will measure telomerase activity by using PCR- ELISA, ADMA and sCD163 by ELISA kits and expression of interleukin 6 and TNF-alpha genes with real-time PCR. Questionnaires will be filled up and 3 day food record forms will be delivered to patients to fill them in first and last week of intervention. 4) Participants: 72 T2DM patients (males and females); Age from 30 to 70 years old and Body Mass Index from 18.5 to 30 kg/m² Main exclusion criteria: Insulin therapy; any type of Cancer; Liver, Kidney, Coagulation, Thyroid, Cardiovascular disorders; consumption of Anticoagulants, anti-inflammatory drugs; Fibrates; Thiazolidinedione's; Supplementation with omega-3, vitamin A,D and B6 5) Intervention: Participants will receive 2 gram per day DHA or placebo (Sunflower oil) capsules, for 8 weeks. 6) Main outcome variables: Interleukin 6 gene expression, TNF- α gene expression, ADMA, sCD163, Telomerase activity, Total cholesterol, Triglyceride, HDL- cholesterol, LDL-cholesterol, Fasting Blood Sugar, Fasting insulin, Insulin resistance, Glycated hemoglobin

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013071213964N1**
Registration date: **2013-09-15, 1392/06/24**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-09-15, 1392/06/24

Registrant information

Name

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Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

1) Tehran University of Medical Sciences 2) Endocrinology and Metabolism Research Institute of Tehran University

Expected recruitment start date

2013-09-06, 1392/06/15

Expected recruitment end date

2014-02-04, 1392/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of DHA supplementation on factors influencing vascular thickness and intima-media smooth muscle proliferation in patients with type 2 diabetes mellitus

Public title

The effect of Docosahexaenoic acid on factors influencing vascular thickness and function in diabetic patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Type 2 diabetic patients (both males and females); 30-70 years old age; BMI range between 18.5 to 35 kg/m² Exclusion criteria: Insulin therapy; any type of Cancer; Liver, Kidney, Coagulation and Thyroid disorders; Cardiovascular diseases such as Angina Pectoris, Myocardial infarction, Stroke; consumption of Anticoagulants, ant-inflammatory and lipid lowering agents such as Fibrates; Thiazolidinedione's therapy; History of Allergic reaction to fish or fish oil; Daily consumption of fish or fish oil supplements; Supplementation with vitamin A,D and B6; Pregnancy and Lactating; lack of usage more than 10% of administered tablets.

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **72**

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

School of Nutrition and diet therapy, Tehran University of Medical Sciences, 16 Azar Ave, Enghelab Sq., Tehran

City

Tehran

Postal code

1417653761

Approval date

2013-07-13, 1392/04/22

Ethics committee reference number

2229187101

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

Type 2 Diabetes melitus

ICD-10 code

E11

ICD-10 code description

non-insulin-dependent diabetes

2**Description of health condition studied**

Atherosclerosis

ICD-10 code

I70

ICD-10 code description

Arterial sclerosis

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

Interleukin 6 gene expression

Timepoint

start and end of intervention

Method of measurement

Real time PCR

2**Description**

TNF- α gene expression

Timepoint

start and end of intervention

Method of measurement

Real time PCR

3**Description**

ADMA

Timepoint

start and end of intervention

Method of measurement

ELISA

4

Description

sCD163

Timepoint

start and end of intervention

Method of measurement

ELISA

5

Description

Telomerase activity

Timepoint

start and end of intervention

Method of measurement

PCR-ELISA kit

6

Description

Total cholesterol

Timepoint

start and end of intervention

Method of measurement

Turbidimeter

7

Description

Triglyceride

Timepoint

start and end of intervention

Method of measurement

Turbidimeter

8

Description

HDL- cholesterol

Timepoint

start and end of intervention

Method of measurement

Turbidimeter

9

Description

LDL-cholesterol

Timepoint

start and end of intervention

Method of measurement

Friedewald formula

10

Description

Fasting Blood Sugar

Timepoint

start and end of intervention

Method of measurement

Turbidimeter

11

Description

Fasting insulin

Timepoint

start and end of intervention

Method of measurement

ELISA

12

Description

Insulin resistance

Timepoint

start and end of intervention

Method of measurement

Formula

13

Description

Glycated hemoglobin

Timepoint

start and end of intervention

Method of measurement

Kit

Secondary outcomes

1

Description

Vascular function and proliferation of smooth muscle cells in intima media

Timepoint

start and end of intervention

Method of measurement

Studying the effective factors in vascular function and proliferation of smooth muscle cells in intima media and also comparison of these factors in two intervention and control groups

Intervention groups

1

Description

Intervention group: DHA supplement (2 gr per day , 3 month)

Category

Treatment - Drugs

2

Description

Control group: Placebo capsule (containing Sunflower oil similar to DHA capsule) with similar dose (2 gr per day) and similar period (3 month)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic of Endocrinology and Metabolism
Research Institute of Tehran University

Full name of responsible person

Dr Ensieh Nasli

Street address

Endocrinology and Metabolism Research Institute,
Shariati Hospital, North Karegar Avenue, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

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University of Medical Sciences, 16 Azar Ave, Enghelab
Sq, Tehran

City

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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. Ensieh Nasli

Street address

Endocrinology and Metabolism Research Institute,
Shariati Hospital, North Karegar Avenue, Tehran, Iran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

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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

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Position

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Person responsible for scientific inquiries

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Full name of responsible person

Omid Toupchan

Position

PhD candidate in Nutrition and Diet Therapy

Other areas of specialty/work**Street address**

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Tehran

Postal code**Phone****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