

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of Omega 3 supplementation on oxidative stress & the gene expression of sestrin 2 enzyme & Nrf2 factor in diabetic patient type 2

Protocol summary

Study aim

Evaluation of the effect of Omega 3 supplementation (eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) on lipid profile, and sestrin 2 and Nrf2 gene expression in patients with type 2 diabetes

Design

70 patients with type 2 diabetes are divided into 2 groups of drug and placebo. The patients will be allocated randomly to either groups using permuted block randomization. Codes will be assigned to patients for concealment.

Settings and conduct

This randomized double blind clinical trial is performed on 70 patients with type 2 diabetes admitted to Diabetes Clinic of Tehran University of Medical Sciences. Neither the patients nor the physician are aware of the type of supplement that is administered. In the beginning of the study fasting blood samples are collected and used for the measurement of insulin, blood glucose, lipid profile. After the initial clinical and biochemical investigations all the patients are given either 2700 mg n3PUFA in the form of oral capsules or oral paraffin as the placebo in three divided doses for ten weeks. Blood samples are collected and all the above biochemical parameters including insulin, sestrin and NRF-2 gene expression and total antioxidant levels are measured. Before and after intervention diet input, anthropometric characteristics, systolic and diastolic blood pressure are measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having type 2 diabetes, BMI within 25-40 kg/m² range, men 30-65 yr, women 30 yr-before menopause Exclusion criteria: having other diseases, taking drugs which may affect obesity or metabolism, pregnancy and lactation.

Intervention groups

Drug group: treatment with n-3PUFA supplement, 2700 mg (combination of EPA=1800 mg and DHA=900 mg) for 10 weeks Placebo group: treatment with oral paraffin for 10 weeks.

Main outcome variables

sestrin expression, NRF2 transcription factor gene expression

General information

Reason for update

Based on the calculations of sample size, the sample size that is stated in the "randomization section" (70 participants) is correct and the sample size 80 was entered mistakenly and must be corrected.

Acronym

IRCT registration information

IRCT registration number: **IRCT20150926024198N4**

Registration date: **2018-01-28, 1396/11/08**

Registration timing: **retrospective**

Last update: **2020-01-30, 1398/11/10**

Update count: **1**

Registration date

2018-01-28, 1396/11/08

Registrant information

Name

Mitra Nourbakhsh

Name of organization / entity

Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01
Expected recruitment end date
 2016-10-22, 1395/08/01
Actual recruitment start date
 2015-08-22, 1394/05/31
Actual recruitment end date
 2017-11-22, 1396/09/01
Trial completion date
 2018-03-01, 1396/12/10

Scientific title
 The effect of Omega 3 supplementation on oxidative stress & the gene expression of sestrin 2 enzyme & Nrf2 factor in diabetic patient type 2

Public title
 The effect of Omega 3 supplementation on oxidative stress in patients with type 2 diabetes

Purpose
 Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Diabetic patients with diabetes duration more than one year. Diabetic patient in both genders, men 36-65 years old and women from 30 years old upto before menopause. BMI in the range of 25-40 kg/m2. Literateness (for recording 3-day meal) Willingness to maintain weight during the study. Willingness to maintain routine activities and current lifestyle during the study. Willingness to participate in the study
Exclusion criteria:
 pregnancy and lactation Consumption of omega-3 supplement in the last three months. having chronic renal, hepatic, enteric, haematic disorders, microalbuminuria, retinopathy, neuropathy, hypo/hyperthyroidism, cardiac disease, type 1 diabetes according to patient declaration and medical history. Treatmetn with orlistat, cybotramin, insulin, thiazolidinediones, non-steroidical anti-inflammatory drugs Using Combined oral contraceptive pills Using dietary supplements, vitamin supplements, and herbal supplements at least 2 weeks before intervention Changing dose or type of anti-diabetic drug Occurrence of any inflammatory disease which requires using anti-inflammation drugs. Unwillingness to continue participation. Using less than 90 percent of the omega 3 supplement. Appearance of any allergic reactions to omega-3.

Age
 From **30 years** old to **65 years** old

Gender
 Both

Phase
 3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
 Target sample size: **70**
 Actual sample size reached: **61**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Randomization will be performed by permuted block randomization method using block of size 4. according to sample size which is 70, 18 blocks of 4 will be produced using www.sealedenvelope.com. In order to perform concealment, unique codes, produced by software, will be assigned to each participant will be used so that no one is informed about the type of intervention prior to selection.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 In this study the patients are blinded. The placebo has been provided in a form similar to the main drug and each one is indicated by a code that only the main investigator is aware of. The patients do not know whether they are using the main drug or the placebo. The physician who is responsible for physical examination of the patient and administering the supplement is also blinded and not aware of the codes and only delivers the supplements to the patients. Data analyzer is also blinded and analyzes the data according to two separate groups.

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Hemmat Highway

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1449614535

Approval date

2017-09-06, 1396/06/15

Ethics committee reference number

IR.IUMS.REC 1396.1213

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

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

Sestrin gene expression

Timepoint

10 weeks

Method of measurement

Real time- polymerase chain reaction (PCR)

2**Description**

NRF2 transcription factor gene expression

Timepoint

10 week

Method of measurement

Real-time PCR

3**Description**

Serum total antioxidants

Timepoint

10 weeks

Method of measurement

spectrophotometry

Secondary outcomes**1****Description**

Weight

Timepoint

10 weeks

Method of measurement

Scale

2**Description**

BMI

Timepoint

10 weeks

Method of measurement

Calculation according to weight and height using relevant formula

3**Description**

Insulin

Timepoint

10 weeks

Method of measurement

ELISA test

4**Description**

A1C hemoglobin

Timepoint

10 weeks

Method of measurement

spectrophotometry

5**Description**

Malondialdehyde

Timepoint

10 weeks

Method of measurement

colorimetry

6**Description**

Fasting blood glucose

Timepoint

10 weeks

Method of measurement

colorimetry

7**Description**

HOMA-IR

Timepoint

10 weeks

Method of measurement

calculation

Intervention groups**1****Description**

Intervention with omega 3 polyunsaturated fatty acid supplement by the daily dose of 1250 mg (combination of EPA=600 mg and DHA= 300 mg) for 10 weeks.

Category

Treatment - Drugs

2**Description**

Control group: oral paraffin for 10 weeks

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Diabetes Clinic of Tehran University of Medical

Sciences

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Dr. Maryam Mazaherion

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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number

96-02-30-31213

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

Maryam Mazaherioon

Position

Non-faculty researcher

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available

Title and more details about the data/document

All collected deidentified results from primary and
secondary outcomes

**When the data will become available and for how
long**

After publication of results

To whom data/document is available

Researchers from academic that applies

Under which criteria data/document could be used

For systematic analysis

From where data/document is obtainable

Contacting the person responsible for scientific
enquiries

**What processes are involved for a request to access
data/document**

two month

Comments