

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The assesment of the effects of omega 3 faty acid supplementation on serum level of Omentin , Chemerin and TNF-alpha in patients with type 2 diabetes mellitus

Protocol summary

Summary

Objective: The effect of omega 3 fatty acids supplementation in adult with type 2 of diabetes mellitus
Study design Randomized, double-blind, placebo-controlled, single-center, trial study (phase II) population: Adults with Type 2 Diabetes Referring to the Iranian Diabetes Center inclusion criteria: 30-65 years of age, T2DM diagnosis, and BMI in the range of 18.5 to 40 kg/m2 exclusion criteria: Unwillingness to cooperate, change the dose or type of anti-diabetes drug, incidence of any sensitivity Interventions: omega 3 supplementation and placebo Intervention period: 10 weeks outcomes: plasma levels of omentin, chemerin and TNF-a

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017092724081N3**

Registration date: **2017-11-01, 1396/08/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-01, 1396/08/10

Registrant information

Name

Niaz Mohammadzade Honarvar

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 4461

Email address

honarvar@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran university of medical sciences

Expected recruitment start date

2012-01-01, 1390/10/11

Expected recruitment end date

2012-05-01, 1391/02/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The assesment of the effects of omega 3 faty acid supplementation on serum level of Omentin , Chemerin and TNF-alpha in patients with type 2 diabetes mellitus

Public title

The effects of omega-3 fatty acids supplementation on type 2 diabetes mellitus

Purpose

Supportive

Inclusion/Exclusion criteria

The criteria for inclusion were as follows: 30-65 years of age; T2DM diagnosis; and BMI in the range of 18.5 to 40 kg/m2. Patients with a history of diseases including chronic renal; hepatic; gastrointestinal; hematological diseases; and thyroid disorder as well as pregnant and lactating patients were excluded from the study. Furthermore, Patients who were treated with insulin; Thiazolidinediones or consumed weight loss drugs and any nutritional supplement 2 weeks prior to the beginning of the study were excluded from the study.

The exclusion criteria: Unwillingness to cooperate; change the dose or type of anti-diabetes drug; incidence of any sensitivity Interventions.

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **20**

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

Ethic committee of Tehran university of medical sciences

Street address

16 azar St., Keshavarz Blvd

City

Tehran

Postal code

1366736511

Approval date

2016-02-16, 1394/11/27

Ethics committee reference number

IR.TUMS.REC.1394.1989

Health conditions studied

1

Description of health condition studied

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

omentin

Timepoint

Pre-intervention/10 weeks after intervention

Method of measurement

ELISA - mg/dl

2

Description

chemerin

Timepoint

Pre-intervention/10 weeks after intervention

Method of measurement

ELISA - mg/dl

3

Description

TNF-alpha

Timepoint

Pre-intervention/10 weeks after intervention

Method of measurement

ELISA - pg/dl

Secondary outcomes

1

Description

Insulin

Timepoint

Pre-intervention/10 weeks after intervention

Method of measurement

ELISA/ μ U/ml

2

Description

HOMA-IR

Timepoint

Pre-intervention/10 weeks after intervention

Method of measurement

fasting insulin (μ U/ml) \times fasting glucose (mmol/ml)/22.5

3

Description

QUICKI

Timepoint

Pre-intervention/10 weeks after intervention

Method of measurement

$1/\{\log[\text{fasting insulin } (\mu\text{U/mL})] + \log[\text{fasting glucose } (\text{mg/dL})]\}$

Intervention groups

1

Description

Intervention group: four softgels of ω -3 per day, containing 310 mg EPA, 210 mg DHA, 110 mg other polyunsaturated fatty acids and five mg vitamin E

Category

Treatment - Drugs

2

Description

Control group: four placebo softgels a day, containing paraffin oil with the same size and color as ω -3 fatty acid soft gels

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian Diabetic Association

Full name of responsible person

Mohammad prohan

Street address

Number27,Ramin Malekoti alley,Patris street,
Satarkhan street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of
Medical Sciences

Full name of responsible person

Dr.younesian

Street address

Sixth Floor, Central Department of University, Ghods
St., Keshavarz Blvd

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical
Sciences

Proportion provided by this source

100

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

Niaz Mohammadzade Honarva

Position

Assistant professor/PhD Nutrition Sciences

Other areas of specialty/work

Street address

Department of Nutrition and Dietetic, Hojat doost
Alley, Naderi St, Keshavarz Blvd, Tehran

City

Tehran

Postal code

Phone

+98 21 8897 4461

Fax

Email

honarvar@tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Niaz Mohammadzade Honarvar

Position

PhD Nutrition Sciences

Other areas of specialty/work

Street address

Department of Nutrition and Dietetic, Hojat doost
Alley, Naderi St, Keshavarz Blvd, Tehran

City

Tehran

Postal code

Phone

+98 21 8897 4461

Fax

Email

honarvar@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Niaz Mohammadzade Honarvar

Position

Assistant professor/PhD Nutrition Sciences

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

Department of Nutrition and Dietetic, Hojat doost
Alley, Naderi St, Keshavarz Blvd, Tehran

City

Tehran

Postal code**Phone**

+98 21 8897 4461

Fax**Email**

honarvar@tums.ac.ir

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