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

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Niaz Mohammadzade Honarvar
Name of organization / entity
Tehran University of Medical Sciences
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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/µIU/ml

2

Description
HOMA-IR

Timepoint
Pre-intervention/10 weeks after intervention

Method of measurement
fasting insulin (µIU/ml) × fasting glucose (mmol/ml)/22.5

3

Description
QUICKI

Timepoint
Pre-intervention/10 weeks after intervention

Method of measurement
1/{log[fasting insulin (µU/mL)] + log[fasting glucose (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 streeet
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
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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