Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Effect of omega-3 fatty acid supplementation on homocysteine, lipid profile and insulin resistance in patients with diabetes mellitus

Protocol summary

Summary

This study is a double-blind placebo-controlled clinical trial. the aim of the study is to determine the effects of omega-3 supplementation on serum homocysteine level, lipid profile and insulin resistance in diabetic patients. 70 patients 20-60 years of age with diagnosed diabetes that had been detected by Yazd Diabetes Research Center, After filling out the consent, will be recruited to the study. Period of intervention is 6 weeks. According to random assignment, patients will be divided into two groups: 1) 2 gr/day of Omega-3 soft gels a, or 2) 2 gr/day of Polyethylene glucose soft gels (as placebo). Anthropometric and biochemical measurements, medical and general information and 24-hour dietary recalls will be collected at the beginning and end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013011312122N1**
Registration date: **2013-01-29, 1391/11/10**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-01-29, 1391/11/10

Registrant information

Name

Faezeh Poursoleiman

Name of organization / entity

Yazd Shahid Sadoughi University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Department of Health, Yazd Shahid Sadoughi University of Medical Sciences.

Expected recruitment start date

2013-04-09, 1392/01/20

Expected recruitment end date

2013-08-11, 1392/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of omega-3 fatty acid supplementation on homocysteine, lipid profile and insulin resistance in patients with diabetes mellitus

Public title

Effect of omega-3 fatty acid supplementation on diabetes mellitus patients

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: patients with diagnosed diabetes and age of 25 to 60 years; a minimum of 5 years experience in diabetes; without any kidney; liver heart; thyroid, bleeding disorders or malignancies; not taking omega-3 supplements in recent months; not using insulin therapy; not pregnant or lactating. exclusion criteria: taking less than 80% of soft gels; changing the type and dose of routine medicine; consume B vitamins supplements during the study.

Age

From **25 years** old to **60 years** old

Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
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
Department of Health, Yazd Shahid Sadoughi University of Medical Sciences.
Street address
University Department, Bahonar square
City
Yazd
Postal code
Approval date
2013-01-06, 1391/10/17
Ethics committee reference number
17/142108/پ

Health conditions studied

1

Description of health condition studied
type 2 diabetes
ICD-10 code
E11
ICD-10 code description
Non-insulin dependent diabetes mellitus

Primary outcomes

1

Description
serum homocysteine
Timepoint
baseline and after 6 weeks
Method of measurement
enzymatic cycling using Reagent kit

2

Description
fasting blood glucose
Timepoint
baseline and after 6 weeks
Method of measurement
enzymatic

3

Description
fasting serum insulin
Timepoint
baseline and after 6 weeks
Method of measurement
ELISA assay

4

Description
Insulin resistance
Timepoint
baseline and after 6 weeks
Method of measurement
HOMA-IR calculation

5

Description
beta cells function
Timepoint
baseline and after 6 weeks
Method of measurement
HOMA-IR calculation

6

Description
serum Triglycerides
Timepoint
baseline and after 6 weeks
Method of measurement
enzymatic

7

Description
total Cholesterol
Timepoint
baseline and after 6 weeks
Method of measurement
enzymatic

8

Description
HDL- Cholesterol
Timepoint
baseline and after 6 weeks
Method of measurement

enzymatic

9

Description
LDL-Cholesterol
Timepoint
baseline and after 6 weeks
Method of measurement
Friedewald formula

10

Description
Insulin sensitivity
Timepoint
baseline and after 6 weeks
Method of measurement
HOMA-IR calculation

Secondary outcomes

empty

Intervention groups

1

Description
omega-3, 1 gr soft gel, twice a day for 6 weeks
Category
Treatment - Drugs

2

Description
placebo capsule containing inert Polyethylene glucose, 1 gr soft gel, twice a day for 6 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd Diabetes Research Center
Full name of responsible person
Dr Hasan Mozaffari Khosravi
Street address
Diabetes Center, Afshar hospital, Jomhuri Blvd
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd Shahid Sadoughi University of Medical Sciences.
Full name of responsible person
Dr Hasan Mozaffari Khosravi (Director of Research in Shahid Sadugho university)
Street address
Department of Health, Imam Reza building, Student Blvd, Imam Hossein Square
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd Shahid Sadoughi 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
Yazd Shahid Sadoughi University of Medical Sciences.
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Person responsible for scientific inquiries

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Person responsible for updating data

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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