

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 1623 4120

##### Email address

f.poursoleiman@ssu.ac.ir

##### 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.

##### Full name of responsible person

Faezeh Poursoleiman

##### Position

Student of MSc Health Sciences in Nutrition

##### Other areas of specialty/work

##### Street address

Graduate Units, Department of Health, Imam Reza building, Student Blvd, Imam Hossein Square

##### City

Yazd

##### Postal code

##### Phone

+98 35 1623 4120

##### Fax

##### Email

f.poursoleiman@ssu.ac.irf\_po\_yazd@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Yazd Shahid Sadoughi University of Medical Sciences

##### Full name of responsible person

Dr Hasan Mozaffari Khosravi

##### Position

PhD in Nutritional Sciences

##### Other areas of specialty/work

##### Street address

Department of Health, Imam Reza building, Student Blvd, Imam Hossein Square

**City**

Yazd

**Postal code**

**Phone**

+98 35 1724 0173

**Fax**

**Email**

mozaffari.kh@gmail.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Yazd Shahid Sadoughi University of Medical Sciences.

**Full name of responsible person**

Faezeh Poursoleiman

**Position**

Student of MSc Health Sciences in Nutrition

**Other areas of specialty/work**

**Street address**

Department of Health, Graduate Units, Imam Reza building, Student Blvd, Imam Hossein Square

**City**

Yazd

**Postal code**

**Phone**

+98 35 1623 4120

**Fax**

**Email**

f\_po\_yazd@yahoo.comf.poursoleiman@ssu.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*