

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### The effect of omega 3 polyunsaturated fatty acid supplementation on Glycemic indicators, Lipid profile and liver function in patients with Type 2 Diabetes and Nonalcoholic Fatty Liver Disease.

#### 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 glycemic index, lipid profile and liver function in patients with type 2 diabetes and non-alcoholic fatty liver disease. 60 patients 18-60 years of age with diagnosed diabetes and non-alcoholic fatty liver disease. After filling out the consent, will be recruited to the study. Period of intervention is 12 weeks. According to random assignment, patients will be divided into two groups: 1) 2 gr/day of Omega-3 soft gels (Mercury free), or 2) 2 gr/day of edible paraffin 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: **IRCT2016102530489N1**

Registration date: **2017-02-06, 1395/11/18**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-02-06, 1395/11/18

##### Registrant information

###### Name

Zahra Orang

###### Name of organization / entity

Yazd Shahid Sadoughi University of Medical Sciences

###### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3820 9100

##### Email address

orang.zahra@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

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

##### Expected recruitment start date

2016-08-22, 1395/06/01

##### Expected recruitment end date

2017-03-20, 1395/12/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of omega 3 polyunsaturated fatty acid supplementation on Glycemic indicators, Lipid profile and liver function in patients with Type 2 Diabetes and Nonalcoholic Fatty Liver Disease.

##### Public title

Effect of omega-3 fatty acid supplementation in patients with Type 2 Diabetes and Nonalcoholic Fatty Liver Disease.

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria include type II diabetes, nonalcoholic fatty liver disease, non-participation in the intervention program, ranging in age from 18 to 60 years, both men and women, not using insulin therapy, without any kidney; liver heart; thyroid, bleeding disorders or

malignancies and lack of special diet Exclusion criteria from the study: type1 diabetes,alcoholic fatty liver disease, hepatitis type B and C, abuse alcohol, consume drugs and blood thinners such as warfarin, heparin or pentoxifylline, who recently had surgery, having allergic to seafood, uncontrolled high blood pressure, a weakened immune system and use drugs that cause fatty liver, such as steroids, estrogen, amiodarone, tamoxifen in the last 6 months

#### Age

From **18 years** old to **60 years** old

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **60**

#### 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, Alam square

##### City

Yazd

##### Postal code

##### Approval date

2016-08-14, 1395/05/24

##### Ethics committee reference number

IR.SSU.SPH.REC.1395.67

## 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

### 2

#### Description of health condition studied

Nonalcoholic fatty liver disease (NAFLD)

#### ICD-10 code

K76.0

#### ICD-10 code description

Fatty (change of) liver, not elsewhere classified (NAFLD)

## Primary outcomes

### 1

#### Description

HbA1c

#### Timepoint

baseline and after 12 weeks

#### Method of measurement

ELISA

### 2

#### Description

FBS

#### Timepoint

baseline and after 12 weeks

#### Method of measurement

enzymatic

### 3

#### Description

ALT

#### Timepoint

baseline and after 12 weeks

#### Method of measurement

photometric assay

### 4

#### Description

AST

#### Timepoint

baseline and after 12 weeks

#### Method of measurement

photometric assay

### 5

#### Description

GGT

#### Timepoint

baseline and after 12 weeks

#### Method of measurement

Enzymatic colorimetric assay

### 6

#### Description

serum Triglycerides

**Timepoint**

baseline and after 12 weeks

**Method of measurement**

enzymatic

**7****Description**

total Cholesterol

**Timepoint**

baseline and after 12 weeks

**Method of measurement**

enzymatic

**8****Description**

HDL- Cholesterol

**Timepoint**

baseline and after 12 weeks

**Method of measurement**

enzymatic

**9****Description**

LDL-Cholesterol

**Timepoint**

baseline and after 12 weeks

**Method of measurement**

Friedewald formula

**Secondary outcomes**

empty

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

omega-3, 1 gr soft gel, twice a day for 12 weeks

**Category**

Placebo

**2****Description**

placebo capsule containing Paraffin food, 1 gr soft gel, twice a day for 12 weeks

**Category**

Placebo

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

Shiraz Martyr Faghihi Hospital

**Full name of responsible person****Street address****City**

Shiraz

**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**

University Department, Alam 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**

Zahra Orang

**Position**

Student of MSc Health Sciences in Nutrition

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

University Department, Alam square

**City**

Yazd

**Postal code****Phone**

+98 353820910014

**Fax****Email**

mozaffari.kh@gmail.com/orang.zahra@ssu.ac.ir/zahra orang72@gmail.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**

University Department, Alam square

**City**

Yazd

**Postal code**

**Phone**

+98 35 3820 9143

**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**

Zahra Orang

**Position**

Student of MSc Health Sciences in Nutrition

**Other areas of specialty/work**

**Street address**

**City**

Shiraz

**Postal code**

**Phone**

00

**Fax**

**Email**

zahraorang72@gmail.com

**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*