

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### The effect of omega 3 polyunsaturated fatty acid supplementation on inflammatory markers and insulin resistance factors 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 inflammatory markers and insulin resistance factors in patients with type 2 diabetes and non-alcoholic fatty liver disease. 48 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: **IRCT2017103030489N2**  
Registration date: **2017-11-16, 1396/08/25**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-11-16, 1396/08/25

##### 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

2016-12-21, 1395/10/01

##### Expected recruitment end date

2017-06-20, 1396/03/30

##### 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 inflammatory markers and insulin resistance factors in patients with Type 2 Diabetes and Nonalcoholic Fatty Liver Disease

##### Public title

The effect of omega 3 polyunsaturated fatty acid supplementation on inflammatory markers and insulin resistance factors in patients with Type 2 Diabetes and Nonalcoholic Fatty Liver Disease

##### Purpose

Prevention

##### 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: **48**

**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**

2017-01-31, 1395/11/12

**Ethics committee reference number**

IR.SSU.SPH.REC.1395.143

**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**

Fasting Insulin serum

**Timepoint**

baseline and after 12 weeks

**Method of measurement**

ELISA

**2****Description**

TNF- $\alpha$

**Timepoint**

baseline and after 12 weeks

**Method of measurement**

ELISA

**3****Description**

IL-6

**Timepoint**

baseline and after 12 weeks

**Method of measurement**

ELISA

**4****Description**

hs-CRP

**Timepoint**

baseline and after 12 weeks

**Method of measurement**

By Laboratory Kit

**5****Description**

HOMA-IR

**Timepoint**

baseline and after 12 weeks

**Method of measurement**

Blood Sampling and putting glucose and insulin levels in formula

## 6

### Description

HOMA-β

### Timepoint

baseline and after 12 weeks

### Method of measurement

Blood Sampling and putting glucose and insulin levels in formula

## 7

### Description

QUICKI

### Timepoint

baseline and after 12 weeks

### Method of measurement

formula calculation

## 8

### Description

Beta cell function

### Timepoint

baseline and after 12 weeks

### Method of measurement

HOMA2 calculator software

## 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

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Yazd Shahid Sadughi University of Medical Sciences

##### Full name of responsible person

Dr Hasan Mozaffari Khosravi

**Position**

PhD in Nutritional Sciences

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**Position**

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**Email**

orang.zahra@ssu.ac.ir/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*