

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

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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- α

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

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Full name of responsible person

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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