Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 2026

The effect of omega 3 polyunsaturated fatty acid supplementation on inflammatory markers and insulin resistanse 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 resistanse 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

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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 resistanse 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 resistanse 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
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Student of MSc Health Sciences in Nutrition
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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person

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PhD in Nutritional Sciences

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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