Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

The effect of a hypocaloric diet and omega-3 fatty acid supplementation on serum levels of liver enzymes, lipid profile and insulin resistance in overweight and obese patients with non-alcoholic fatty liver disease

Protocol summary

Summary

Aim: This study's aim is to compare the effect of a 12 weeks hypocaloric diet and omega-3 fatty acid supplementation on serum levels of liver enzymes, lipid profile and insulin resistance in overweight and obese patients with Nafld. Methods: This study is a randomized controlled trial. One hundred and fourteen overweight and obese patients with Nafld will randomize (stratified block randomization method) to receive a hypocaloric diet consisting of 50% carbohydrates, 20% protein and 30% fat with a goal of 5% weight reduction, or take 2 omega-3 fatty acids capsules per day providing 1500 mg EPA+DHA or be provided with no intervention for 12 week. Fasting blood samples (to measure alanine aminotransferase, aspartate aminotransferase, HDL-C, LDL-C, TG, TC, FBS, insulin), HOMA-IR, anthropometric measurements (weight, height, WC), physical activity and dietary intake data will be collected at baseline and at the end of the trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016082429508N1**
Registration date: **2016-09-20, 1395/06/30**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-09-20, 1395/06/30

Registrant information

Name

Rasoul Zarrin

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Urmia University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a hypocaloric diet and omega-3 fatty acid supplementation on serum levels of liver enzymes, lipid profile and insulin resistance in overweight and obese patients with non-alcoholic fatty liver disease

Public title

The effect of hypocaloric diet and omega-3 fatty acid supplementation on overweight and obesity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18 and 65 years; the diagnosis of Nafld is established by the presence of steatosis of the liver on ultrasound associated with a

persistent increase in alanine aminotransferase (ALT) and aspartate aminotransferase (AST) of 1.5-4 times the upper limit of normal and AST:ALT<1; body mass index between 25 and 40 kg/m2; having informed consent. Exclusion criteria: pregnancy and lactation; alcohol consumption; substance abuse; engaging in strenuous exercise; any known pathological condition affecting the liver, e.g., autoimmune liver disease, hepatic virus infection, hepatobiliary disease,history of liver transplantation, hereditary defects (Wilson disease, hemochromatosis, ...), neoplasm, cardiovascular disease, endocrine disorders (diabetes mellitus, untreated hypothyroidism,...), bariatric surgery within the past year, engagement in an active weight loss program or taking weight-loss medication within the 3 months before the study, omega-3 fatty acid supplementation within the 3 months before the study; treatment with some medications (anticoagulant drugs, insulin-sensitizing drugs, statins, vitamin E), steatogenic and hepatotoxic medications and use of any medicine or dietary supplement that could influence glucose and lipid metabolism within the 3 months before the study.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **114**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Urmia University of Medical Sciences

Street address
UMSU Central Site,Orjhans Street, Resalat Blvd, Urmia , Iran

City
Urmia

Postal code
571478334

Approval date
2016-08-31, 1395/06/10

Ethics committee reference number
IR.UMSU.REC.1395.222

Health conditions studied

1

Description of health condition studied
Non-alcoholic fatty liver disease

ICD-10 code
K76.0

ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Fasting blood sugar

Timepoint
At baseline and after 3 month

Method of measurement
measured in milligram per deciliter, using colorimetry method

2

Description
Fasting insulin

Timepoint
At baseline and after 3 month

Method of measurement
measured in microUnit/milliliter, using Elisa

3

Description
HOMA-IR

Timepoint
At baseline and after 3 month

Method of measurement
using formula

4

Description
High density lipoprotein (HDL-C)

Timepoint
At baseline and after 3 month

Method of measurement
measured in milligram per deciliter, using colorimetry method

5

Description
Low density lipoprotein (LDL-C)

Timepoint

At baseline and after 3 month

Method of measurement

measured in milligram per deciliter, using colorimetry method

6

Description

Total cholesterol

Timepoint

At baseline and after 3 month

Method of measurement

measured in milligram per deciliter, using colorimetry method

7

Description

Triglyceride

Timepoint

At baseline and after 3 month

Method of measurement

measured in milligram per deciliter, using colorimetry method

8

Description

Alanine aminotransferase (ALT)

Timepoint

At baseline and after 3 month

Method of measurement

measured in international units/liter, using colorimetry method

9

Description

Aspartate aminotransferase (AST)

Timepoint

At baseline and after 3 month

Method of measurement

measured in international units/liter, using colorimetry method

10

Description

Weight

Timepoint

At baseline and after 3 month

Method of measurement

measured in kilograms, using digital scale

11

Description

Waist circumference

Timepoint

At baseline and after 3 month

Method of measurement

measured in centimeter, using a soft tape

12

Description

Body mass index

Timepoint

At baseline and after 3 month

Method of measurement

kg/m2, using standard formula

13

Description

Height

Timepoint

At baseline and after 3 month

Method of measurement

measured in meter, using mounted tape

Secondary outcomes

1

Description

Physical activity level

Timepoint

At baseline and after 3 month

Method of measurement

international physical activity questionnaire short form (IPAQ-SF)

Intervention groups

1

Description

First intervention group: Thirty eight patients with Nafld will receive a hypocaloric diet program consisting of 50% carbohydrates, 20% protein and 30% fat with a goal of 5% weight reduction. Dietary intake will assess by 24-hour recall method for 3 days and food frequency questionnaire at baseline and the end of the trial. Anthropometric measurements, fasting blood sugar, fasting insulin, lipid profile (TC, LDL-C, HDL-C, TG), HOMA-IR, liver enzyme (ALT and AST) and physical activity data will be collected at baseline and the end of the intervention.

Category

Treatment - Other

2

Description

Second intervention group: Thirty eight patients with Nafld will take 2 omega-3 fatty acids capsules per day providing 1500 mg EPA+DHA. Dietary intake will assess by 24-hour recall method for 3 days at baseline and the end of the trial. Anthropometric measurements, fasting blood sugar, fasting insulin, lipid profile (TC, LDL-C, HDL-C, TG), HOMA-IR, liver enzyme (ALT and AST) and physical activity data will be collected at baseline and the end of the interventio

Category

Treatment - Other

3

Description
Control group: no intervention
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia Emam KHomeini Hospital
Full name of responsible person
Dr. Rasoul Zarrin
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Urmia

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. Iraj Mohebbi
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Urmia
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Urmia 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
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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