

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Investigation of mechanism of supplementation effect with omega-3 on lipid profile and peroxidation , inflammatory markers, insulin resistance and liver function in patients with non-alcoholic fatty liver (NAFL) compared with control group.

Protocol summary

Summary

The aim of this study is to Investigate of mechanism of supplementation effect with omega-3 on lipid profile and peroxidation , inflammatory markers, insulin resistance and liver function in patients with non-alcoholic fatty liver. this is a double blind clinical trial. for confounding variables controlling for sex and Body mass index by subject matching classifying will be done and randomly divided into 2 groups. 40 patients classified into omega-3 treatment group with 20 subjects and placebo group with 20 subjects. After selecting and grouping them under the supervision of a specialist, sampling and assay parameters will perform. patient>18 year with elevated Alanine aminotransfrase for up to 6 month before beginning of the study, lack of excessive alcohol ingestion, ultrasound examination demonstrating fatty liver, negative diagnostic tests for viral hepatitis, and absence of other causes of liver disease. Exclusion criteria included a history of alcohol intake,the use of drugs known to be associated with liver steatosis, undernutrition, chronic viral hepatitis, and chronic liver disease of other causes. Moreover, patients younger than 18 years as well as pregnantand breastfeeding women were excluded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015030721358N1**

Registration date: **2015-04-11, 1394/01/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-04-11, 1394/01/22

Registrant information

Name

Marzieh Ghasemi Falavarjani

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Research Center of Hyperlipidemia, School of Paramedical Sciences, Ahvaz Jundishapur University of Medical Sciences.

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of mechanism of supplementation effect with omega-3 on lipid profile and peroxidation , inflammatory markers, insulin resistance and liver function in patients with non-alcoholic fatty liver (NAFL) compared with control group.

Public title

effect of supplementation with omega-3 in patients with non-alcoholic fatty liver (NAFL)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patient > 18 year; elevated Alanine aminotransferase for up to 6 month before beginning of the study; lack of excessive alcohol ingestion; ultrasound examination; negative diagnostic tests for viral hepatitis; absence of other causes of liver disease. Exclusion criteria: a history of alcohol intake; the use of drugs known to be associated with liver steatosis; undernutrition; pregnant and breastfeeding women.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

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**

Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz, Iran.

City

Ahvaz

Postal code**Approval date**

2015-01-02, 1393/10/12

Ethics committee reference number

ajums.REC.1393.343

Health conditions studied**1****Description of health condition studied**

(Nonalcoholic fatty liver disease (NAFLD

ICD-10 code

K76.0

ICD-10 code description

(Nonalcoholic fatty liver disease (NAFLD

Primary outcomes**1****Description**

lipid profile

Timepoint

before intervention and 2 months after intervention

Method of measurement

mg/dl with autoanalyzer

2**Description**

Inflammatory markers

Timepoint

before intervention and 2 months after intervention

Method of measurement

ELISA

3**Description**

Sugar profile

Timepoint

before intervention and 2 months after intervention

Method of measurement

mg/dl with autoanalyzer

4**Description**

Insulin Resistance

Timepoint

before intervention and 2 months after intervention

Method of measurement

HOMA-IR

Secondary outcomes**1****Description**

Liver enzymes

Timepoint

before intervention and 2 months after intervention

Method of measurement

Autoanalyzer

Intervention groups

1

Description

intervention group: Omega-3 supplement with effective dosage of 900 mg/day, 3*300 mg capsules per day for 2 month

Category

Treatment - Drugs

2

Description

control group: 3 capsules of placebo per day for 2 month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shoushtar's Hospital of Social Security

Full name of responsible person

Dr. Seyed Javad Shariat Nabavi

Street address

Shoushtar's Hospital of Social Security

City

Shoushtar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Saeed Shirali

Street address

Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz Jundishapur 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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

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Phd of Clinical Biochemistry

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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