Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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 randomely 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

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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 aminotransfrase 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; pregnantand 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
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City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
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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

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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