Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Compare the effect of flaxseed and sunflower oil on anthropometric characteristics, pressure and blood lipids and liver enzymes in patients with nonalcoholic fatty liver in overweight patients with a low-calorie diet

Protocol summary

Summary

The aim of study is the effects of flaxseed and sunflower oils on anthropometric characteristics, blood pressure, blood lipids and liver enzymes in overweight patients with nonalcoholic fatty liver in a low-calorie diet. The study is Clinical trial, double-blind, and is performed on 80 patients with non-alcoholic fatty liver randomly divided into two intervention and control group of 40 people. Inclusion criteria: Nonalcoholic fatty liver diseas ;BMI = 25 and above ; lack of type 2 diabetes ; hepatic and cardiovascular disease ;avoiding the use of lipid lowering agents and exclusion criteria: avoid taking diet for more than 15 days in 3 months. Each of the interventional and control groups receive 20 g of flaxseed oil and sunflower oil daily for three months. Diet is calculated separately for each one. 3-day recalls, blood pressure, anthropometric measurements will be taken at the beginning and end of study and end of each month. Blood samples were collected at the beginning and end of the study. The primary outcomes include: changes in body mass index, blood pressure, liver enzymes, lipid profiles, changes in liver fat accumulation and the degree of fatty liver.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011125957N1**
Registration date: **2016-02-07, 1394/11/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-02-07, 1394/11/18

Registrant information

Name

Shahla Rezaei

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Oil Version Factory-School of Nutrition and Food Sciences, Shiraz

Expected recruitment start date

2015-12-16, 1394/09/25

Expected recruitment end date

2017-02-13, 1395/11/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effect of flaxseed and sunflower oil on anthropometric characteristics, pressure and blood lipids and liver enzymes in patients with nonalcoholic fatty liver in overweight patients with a low-calorie diet

Public title

The effect of flaxseed oil in the treatment of non-alcoholic fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: having NAFLD by medical diagnosis (using ultrasound) ; BMI = 25 and above ; willingness to participate in the study, the absence of diabetes mellitus type 2 ;heart disease ;cardiovascular and liver disease (cirrhosis, liver disease Alcohol, viral hepatitis, autoimmune hepatitis, primary biliary cirrhosis, biliary obstruction, liver damage induced by drugs hereditary Hemochromatosis, sclerosis cholangitis and antitrypsin deficiency of α-a-1) ;other serious diseases such as cancer ;kidney failure and celiac disease, etc) ;lack of pregnancy ;lactation ;lack of drugs that are causing fatty liver (methotrexate, tamoxifen, Valproate, etc.) ;avoiding the use of any type of lipid lowering agents (atorvastatin, lovastatin, pravastatin, etc.) ;fibrates (gemfibrozil, fenofibrate) ;lack of malnutrition ;have no special diets such as vegan and vegetarian ;not drinking alcohol and having over 18 years of age. Exclusion criteria: non-compliance with recommended diet for more than 15 days over 3 months ;acute or infectious disease ;hospitalization or in cases where the criteria mentioned is.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

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
Shiraz University of Medical Sciences, School of Nutrition

Street address
Shiraz, Razi Blvd.

City
Shiraz

Postal code

Approval date
2015-12-13, 1394/09/22

Ethics committee reference number
IR.Sums.REC.1394.150

Health conditions studied

1

Description of health condition studied
Nonalcoholic Fatty Liver

ICD-10 code
K76.0

ICD-10 code description
(Nonalcoholic fatty liver disease (NAFLD

Primary outcomes

1

Description
blood pressure

Timepoint
Before the intervention, after the intervention and the end of each month

Method of measurement
Barometer

2

Description
Lipid profile

Timepoint
Before the intervention, after intervention

Method of measurement
blood test

3

Description
Anthropometric indices

Timepoint
Before the intervention, after the intervention and the end of each month

Method of measurement
Devices BIA, scales, meters

4

Description
Liver enzymes

Timepoint
Before the intervention, after intervention

Method of measurement
blood test

5

Description
Changing in the degree of fatty liver

Timepoint
Before the intervention, after the intervention

Method of measurement

Ultrasound

Secondary outcomes

empty

Intervention groups

1

Description
The control group consisted of 40 patients. Randomly placed in this group. 20 grams per day for 3 months receive sunflower oil. Diet and recommendations are presented separately for each person. The exact consumption of oil is measured by graded modules. Outcomes measured before and after the intervention. At the beginning and end of study and end of each month, 3-day recall, blood pressure and anthropometric indices will be taken.
Category
Treatment - Drugs

2

Description
The intervention group consisted of 40 patients. Randomly placed in this group. 20 grams per day for 3 months receive flaxseed oil. Diet and recommendations are presented separately for each person. The exact consumption of oil is measured by graded modules. Outcomes measured before and after the intervention. At the beginning and end of study and end of each month, 3-day recall, blood pressure and anthropometric indices will be taken.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Martyr Motahari clinic
Full name of responsible person
Shahla Rezaei
Street address
Shiraz, Namazi Square
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oil Version Factory
Full name of responsible person
Sales Office
Street address
Gorgan
City
Gorgan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oil Version Factory
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
Department of Food Science and Nutrition
Full name of responsible person
Doctor Masume Akhlaghi
Position
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Other areas of specialty/work
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Person responsible for updating data

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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