

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Aug 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 diseases ;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

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

Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

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Shahla Rezaei
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Master student of nutrition
Other areas of specialty/work
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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