Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Compare the effect of olive oil and sunflower oil on insulin resistance and oxidative stress and inflammatory markers in overweight patients with nonalcoholic fatty liver

Protocol summary

Summary

The aim of study is the effects of olive oil and sunflower oil on insulin resistance, oxidative stress and inflammation markers 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 olive 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 index of insulin resistance, oxidative stress and inflammatory factors TNF alpha. Secondary outcomes: changes in body mass index, blood pressure, waist cercumfrese and degree of fatty liver.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011825957N2**
Registration date: **2016-02-09, 1394/11/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-02-09, 1394/11/20

Registrant information

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Shahla Rezaei
Name of organization / entity
Shiraz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Gorgan-Department of Nutrition and Food Sciences Faculty

Expected recruitment start date

2015-11-03, 1394/08/12

Expected recruitment end date

2016-02-01, 1394/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effect of olive oil and sunflower oil on insulin resistance and oxidative stress and inflammatory markers in overweight patients with nonalcoholic fatty liver

Public title

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

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
From **18 years** old to **70 years** old

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
University of Medical Sciences, School of Nutrition

Street address
Shiraz-Iran Razi

City
Shiraz

Postal code

Approval date
2015-10-31, 1394/08/09

Ethics committee reference number
IR.Sums.REC.1394..103

Health conditions studied

1

Description of health condition studied
Nonalcoholic fatty liver

ICD-10 code
K76.1

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

Primary outcomes

1

Description
Insulin resistance index

Timepoint
The beginning and end of the study

Method of measurement
blood test

2

Description
TNF-Alpha

Timepoint
Before the intervention, after intervention

Method of measurement
blood test

3

Description
Oxidative stress index

Timepoint
Before the intervention, after intervention

Method of measurement
blood test

Secondary outcomes

1

Description
BMI

Timepoint
Beginning of the study and end of each month

Method of measurement
Balance-Meter

2

Description
Changes in body composition (fat and muscle mass)

Timepoint
Before the intervention, after the intervention

Method of measurement
BIA devices

3

Description
The degree of fatty liver
Timepoint
Before the intervention, after the intervention
Method of measurement
Ultrasound

4

Description
Waist Circomfrance
Timepoint
Beginning of the study and end of each month
Method of measurement
Meter

5

Description
blood pressure
Timepoint
Beginning of the study and end of each month
Method of measurement
Barometr

Intervention groups

1

Description
The intervention group consisted of 40 patients. Randomly placed in this group. 20 grams per day for 3 months receive olive 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. Blood samples were also collected before and after the intervention.
Category
Treatment - Other

2

Description
The intervention 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. Blood samples were also collected before and after the intervention.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Martyr Motahari clinic
Full name of responsible person
Shahla Rezaei
Street address
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
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

2

Sponsor
Name of organization / entity
School feeding
Full name of responsible person
Head of School
Street address
Shiraz-Razi Blvd
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

School feeding

Proportion provided by this source

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

Shiraz University Of Medical Sciences

Full name of responsible person

Doctor M. Akhlaghi

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

Department of Nutrition and Food Science

Full name of responsible person

Doctor M.Akhlaghi

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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