

# 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 disease ;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 circumference 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

##### Name

Shahla Rezaei

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3825 7036

##### Email address

shahlarezaei13932014@gmail.com

#### 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  $\alpha$ -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 Circumference

#### **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**

Barometer

## **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  
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## Person responsible for scientific inquiries

### Contact

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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*