

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### Comparison of flaxseed oil and sunflower oil consumption effect on serum triglyceride, HDL-cholesterol, LDL-cholesterol, glucose, MDA and blood pressure in metabolic syndrome patients.

#### Protocol summary

##### Summary

The aim of this study is to assess the flaxseed oil edible consumption effects on metabolic syndrome. Inclusion criteria: waist circumference for men  $\geq 102$  cm and for women  $\geq 88$ cm; fasting blood glucose  $\geq 110$  mg per dl; HDL cholesterol for men  $< 40$  mg per dl and for women  $< 50$  mg per dl; triglycerides  $\geq 150$  mg per dl; systolic blood pressure  $\geq 130$  or diastolic blood pressure  $\geq 85$  mm Hg. Exclusion criteria: liver dysfunction; smoking; kidney disorder and incidence of any inflammatory disease. This randomized controlled clinical trial will be done on 60 metabolic syndrome patients (30 for control and 30 for intervention group) referred to shiraz healthy heart house for 7 weeks. Patient selection randomize will be done in form of block in two groups (control or intervention). Measurement of serum levels of glucose, HDL cholesterol, LDL cholesterol, triglyceride, MDA and blood pressure will be done at the beginning of the study before treatment and end of study in day 49 after consumption daily of 25 cc flaxseed oil (intervention group) or 25 cc sunflower oil (control group).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015012020737N1**

Registration date: **2015-05-23, 1394/03/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-05-23, 1394/03/02

##### Registrant information

Name

Atefe Akrami

##### Name of organization / entity

School of Nutrition, Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3725 7288

##### Email address

akramiat@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Sciences, Vice chancellor for research

##### Expected recruitment start date

2015-04-04, 1394/01/15

##### Expected recruitment end date

2015-05-05, 1394/02/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of flaxseed oil and sunflower oil consumption effect on serum triglyceride, HDL-cholesterol, LDL-cholesterol, glucose, MDA and blood pressure in metabolic syndrome patients.

##### Public title

Assessment of flaxseed oil and sunflower oil consumption effect on serum lipids, glucose, peroxidation lipid factor and blood pressure in metabolic syndrome patients

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: waist circumference men  $\geq$  102cm or 40in and women  $\geq$  88cm or 35in; fasting blood glucose  $\geq$  110 mg per dl; HDL cholesterol for men  $<$  40 mg per dl and for women  $<$  50 mg per dl; triglycerides  $\geq$  150 mg per dl; blood pressure  $\geq$  130 and 85 mm Hg Exclusion criteria: hypothyroidism; alcoholism; smoking; auto immune disease; chronic pancreatitis; liver dysfunction; kidney disorder or nephritic syndrome; simultaneous subscription in other interventional study; any inflammatory disease or incidence of infection at start or during the study period; consumption of other drug such as aspirin or any NSAID; propranolol; any form of steroids and any kind of lipid lowering agent; angioplasty or heart attack positive history; pregnancy and lactating

### **Age**

From **30 years** old to **60 years** old

### **Gender**

Both

### **Phase**

3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **60**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

Randomization in intervention and control group in form of block

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Shiraz University of Medical Sciences

##### **Street address**

Shiraz University of Medical Sciences Ethics Committee, Zand st., Shiraz, Iran

##### **City**

Shiraz

##### **Postal code**

##### **Approval date**

2015-03-10, 1393/12/19

##### **Ethics committee reference number**

93-7420

## **Health conditions studied**

### 1

#### **Description of health condition studied**

metabolic syndrome

#### **ICD-10 code**

E88.9

#### **ICD-10 code description**

Metabolic disorder, unspecified

## **Primary outcomes**

### 1

#### **Description**

Blood Pressure (systolic and diastolic)

#### **Timepoint**

Beginning of study first day and at the end of study 49th day

#### **Method of measurement**

Beurer upper arm digital blood pressure monitor

### 2

#### **Description**

Fasting Blood Glucose

#### **Timepoint**

Beginning of study first day and at the end of study 49th day

#### **Method of measurement**

Laboratory kit, Pars Azmoon

### 3

#### **Description**

Triglyceride

#### **Timepoint**

Beginning of study first day and at the end of study 49th day

#### **Method of measurement**

Laboratory kit, Pars Azmoon

### 4

#### **Description**

HDL-cholesterol

#### **Timepoint**

Beginning of study first day and at the end of study 49th day

#### **Method of measurement**

Laboratory kit, Pars Azmoon

### 5

#### **Description**

waist circumference

#### **Timepoint**

Beginning of study first day and at the end of study 49th day

#### **Method of measurement**

By measure tape least circumference between last rib and iliac crest

## 6

### Description

LDL-cholesterol

### Timepoint

Beginning of study first day and at the end of study 49th day

### Method of measurement

Laboratory kit, Pars Azmoon

## 7

### Description

MDA

### Timepoint

Beginning of study first day and at the end of study 49th day

### Method of measurement

Reaction serum MDA with tiobarbituric acid, measure absorption with florimetry and comparison with standard curve

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

25 cc cold press flaxseed oil daily add to salad or cold food for 7 week

### Category

Treatment - Other

## 2

### Description

25 cc sunflower oil daily add to salad or cold food for 7 week

### Category

Treatment - Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Shiraz Healthy Heart Institute

#### Full name of responsible person

Maryam Rezaei

#### Street address

Healthy Heart Institute, Fazilat St., Modares Blvd., Shiraz, Iran

#### City

Shiraz

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Vice Chancellor for research of Shiraz University of Medical Sciences

#### Full name of responsible person

Ali Poostforush

#### Street address

Vice Chancellor for Research Affairs of Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran

#### City

Shiraz

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Vice Chancellor for research of Shiraz 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

### Contact

#### Name of organization / entity

School of Nutrition, Shiraz University of Medical Sciences

#### Full name of responsible person

Atefe Akrami

#### Position

Msc. Candidate for Nutrition

#### Other areas of specialty/work

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## Person responsible for scientific inquiries

### Contact

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Siavash Babajafari

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Professor Assistant

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**Email**

akramiat@sums.ac.ir; atefe.akrami@yahoo.com

**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*