

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of sesame oil, sesame oil enriched with vitamin E and sunflower oil consumption effect on the lipid profile, glycemia, Malondialdehyde and blood pressure in adults with metabolic syndrome

Protocol summary

Summary

The aim of study is to investigate the effects of sesame oil, sesame oil enriched with vitamin E and sunflower oil on metabolic syndrome. The study is Clinical trial, single blind, and is performed on 75 patients with metabolic syndrome randomly (by block) divided into three groups of 25 people (two experimental groups and one control group). In this way, each group is assigned a number and all possible block size of 3 people found. The blocks were numbered from 1 to 6. Accidentally one of the cards were removed and the number of blocks, the blocks were placed in each of the 75 subjects completed the process to continue. Inclusion criteria: Waist circumference men ≥ 102 cm or 40in and women ≥ 88 cm or 35in, Fasting blood glucose ≥ 100 mg per dl, HDL cholesterol for men < 40 mg per dl and for women < 50 mg per dl, Triglycerides ≥ 150 mg per dl, Blood pressure ≥ 130 and 85 mm Hg. Exclusion criteria: Chronic diseases such as thyroid disease, liver abnormalities and kidney disorders, Allergies to sunflower oil, sesame oil and tocopherol, Consumption of other drug such as Steroids or any NSAID; simultaneous subscription in other interventional study, Pregnancy and lactating. Each of the interventional and control groups receive 30 g of sesame oil, sesame oil enriched with vitamin E and sunflower oil daily for 8 weeks. Diet is calculated separately for each one. 3-day recalls, blood pressure, anthropometric and biochemical measurements will be taken at the beginning and end of study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042233582N1**

Registration date: **2017-07-04, 1396/04/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-04, 1396/04/13

Registrant information

Name

Ali Farajbakhsh

Name of organization / entity

School of Nutrition, Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3726 7056

Email address

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of sesame oil, sesame oil enriched with vitamin E and sunflower oil consumption effect on the lipid profile, glycemia, Malondialdehyde and blood pressure in adults with metabolic syndrome

Public title

Assessment of sesame oil, sesame oil enriched with vitamin E and sunflower oil consumption effect on the lipid profile, glycemia, malondialdehyde and blood pressure in adults with metabolic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Waist circumference men \geq 102cm or 40in and women \geq 88cm or 35in, Fasting blood glucose \geq 100 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: Chronic diseases such as thyroid disease, liver abnormalities and kidney disorders, Allergies to sunflower oil, sesame oil and tocopherol, Consumption of other drug such as Steroids or any NSAID, Simultaneous subscription in other interventional study, Pregnancy and lactating.

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**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

00987132357282

Approval date

2016-12-14, 1395/09/24

Ethics committee reference number

IR.SUMS.REC.1395.154

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**

Fasting blood glucose

Timepoint

Beginning and end of the study

Method of measurement

Blood test

2**Description**

High density lipoprotein-cholesterol

Timepoint

Beginning and end of the study

Method of measurement

Blood test

3**Description**

Serum insulin

Timepoint

Beginning and end of the study

Method of measurement

Blood test

4**Description**

Triglyceride

Timepoint

Beginning and end of the study

Method of measurement

Blood test

5**Description**

Total cholesterol

Timepoint

Beginning and end of the study

Method of measurement

Blood test

6

Description

Low density lipoprotein-cholesterol

Timepoint

Beginning and end of the study

Method of measurement

Blood test

Secondary outcomes

1

Description

Waist circumference

Timepoint

Beginning and end of the study

Method of measurement

Tape measure

2

Description

Malondialdehyde

Timepoint

Beginning and end of the study

Method of measurement

Blood test

3

Description

Blood Pressure (systolic and diastolic)

Timepoint

Beginning and end of the study

Method of measurement

Digital blood pressure monitor

Intervention groups

1

Description

Intervention group 1: Daily intake of 30 grams of sesame oil enriched with vitamin E along with salad or diet for 8 weeks

Category

Other

2

Description

Intervention group 2 : Daily consumption of 30 grams of sesame oil along with salad or diet for 8 weeks

Category

Other

3

Description

Control group : Daily consumption of 30 grams of Sunflower oil along with salad or diet for 8 weeks

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Ali Farajbakhsh

Street address

Namazi Square, Shiraz, Fars

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Ali Poostforush

Street address

Shiraz University of Medical Sciences, Zand Street, Shiraz

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Shiraz University of Medical Sciences

Full name of responsible person

Ali Farajbakhsh

Position

Msc. Candidate for Nutrition

Other areas of specialty/work

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Person responsible for scientific inquiries

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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