Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 ≥ 102cm or 40in and women ≥ 88cm 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 ≥ 102cm or 40in and women ≥ 88cm 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.
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 Commitee of Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences Ethics Commitee, 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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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