Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 ≥ 102 cm and for women ≥ 88cm; fasting blood glucose ≥ 110 mg per dl; HDL cholesterol for men < 40 mg per dl and for women < 50 mg per dl; triglycerides ≥ 150 mg per dl; systolic blood pressure ≥ 130 or diastolic blood pressure ≥ 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

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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 ≥ 102cm or 40in and women ≥ 88cm or 35in; fasting blood glucose ≥ 110 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: 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 Commitee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences Ethics Commitee, 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

Begining 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

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

Method of measurement

Laboratory kit, Pars Azmoon

3

Description

Triglyceride

Timepoint

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

Method of measurement

Laboratory kit, Pars Azmoon

4

Description

HDL-cholesterol

Timepoint

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

Method of measurement

Laboratory kit, Pars Azmoon

5

Description

waist circumference

Timepoint

Begining 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
Begining of study first day and at the end of study 49th day
Method of measurement
Laboratory kit, Pars Azmoon

7

Description
MDA
Timepoint
Begining 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
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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