Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Comparing the effects of flax seed oil vs. sunflower oil consumption on interleukin-6, total antioxidant capacity, and blood coagulation times in metabolic syndrome patients

Protocol summary

Study aim

Comparison of Serum Antioxidant Capacity Changes in Flax Seed and Sunflower Oil Consumers Comparison of Interleukin-6 Serum Levels in Flax Seed and Sunflower Oil Consumers Comparison of PT and PTT changes in flaxseed and sunflower oil consumption groups

Design

The study was performed on 60 patients with metabolic syndrome in control group with parallel groups without blinded randomized block method. And has a phase 3 trial

Settings and conduct

The study will be performed on 60 patients (30 intervention and 30 control in parallel) for 7 weeks referring to Shiraz Healthy Heart Home. Patients will be randomly selected without blinding in blocking. Measurements were taken on the first day of the study, and also on the day of the end of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: waist circumference ≥102 cm or 40 inches for males and ≥88 cm or 35 inches for females, Fasting Blood Sugar (FBS) ≥110 mg/dl, High-Density Lipoprotein-Cholesterol (HDL-C) <40 mg/dl for males and <50 mg/dl for females, fasting Triglyceride (TG) level ≥150 mg/dl, and Systolic Blood Pressure (SBP) ≥130 mm Hg or Diastolic Blood Pressure (DBP) ≥85 mm Hg Exclusion criteria: Hypothyroidism; Alcoholism; Tobacco use; Autoimmune diseases; Chronic pancreatitis; Liver problem; Nephritic syndrome or kidney disorders; Drugs such as aspirin or any other NSAID; propranolol; any steroids; Blood lipid lowering ; history of myocardial infarction or angioplasty; pregnancy and lactation

Intervention groups

Intervention group received 25 cc of flaxseed oil daily (part of daily requirement for fat intake). And control group 25 cc sunflower oil daily. The oil intake will not exceed the daily requirement of participants and no adverse effects have been observed with the use of these oils.

Main outcome variables

interleukin-6; total antioxidant capacity; blood coagulation factors such as PT and PTT.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150120020737N2**
Registration date: **2019-10-04, 1398/07/12**
Registration timing: **retrospective**

Last update: **2019-10-04, 1398/07/12**
Update count: **0**

Registration date

2019-10-04, 1398/07/12

Registrant information

Name

Atefe Akrami

Name of organization / entity

School of Nutrition, Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-14, 1396/01/25

Expected recruitment end date
2017-07-14, 1396/04/23
Actual recruitment start date
2017-04-14, 1396/01/25
Actual recruitment end date
2017-07-14, 1396/04/23
Trial completion date
2017-07-14, 1396/04/23

Scientific title
Comparing the effects of flax seed oil vs. sunflower oil consumption on interleukin-6, total antioxidant capacity, and blood coagulation times in metabolic syndrome patients

Public title
flax seed oil in metabolic syndrome
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
protocol have three or more of the five listed:Abdominal obesity (waist circumference greater than or equal to 102 cm in men and greater than or equal to 88 cm in women)Low HDL-C levels (less than 40 mg / dL in men and less than 50 mg / dL in women)۳ High serum triglyceride level (mg / dL۱۵۰≥)۴ (high blood pressure (130/85 mmHg)) or under hypertension treatment5) impaired glucose homeostasis (110≥F fasting blood glucose level)
Exclusion criteria:
Exclusion criteria include:A history of allergies and allergies to sunflower or seed or two or more types of nuts and seeds,Thyroid diseases (uncontrolled hyperthyroidism),Liver disease (obstruction or biliary disease), liver malformations,Alcoholism, smoking,Autoimmune diseases,Chronic pancreatitis,Kidney problems Nephritic syndrome or kidney disorders (increased blood creatinine more than 1.5 mg / dl),Digestive problems,Simultaneous presence in other clinical trials,Aspirin or any NSAID, propranolol, heparin, warfarin and antiplatelet use (such as Plavix)The presence of any infection or any infectious disease at the beginning or during the study, diabetic foot ulcer,Insulin, Multivitamins and Omega-3 supplements over the past 3 months, any steroids,High blood lipids or medications such as all types of blood lipid lowering agents (statins, gemfibrozil, niacin, lipase inhibitors) or physician discontinuation of blood lipid lowering drugs (at triglyceride levels less than 400 and LDL-C levels lower). Of 170)Hypoglycemic agents are not harmful if used during the past three months and continued during the study. Provided that the dose of the drug is not changed during the study.Also, people with a history of myocardial infarction or angioplasty or any non-outpatient surgery during the 6 months prior to the study,Pregnant and suspected pregnant or lactating women will not be allowed to enter the study.Exclusion criteria: These include: starting taking any of the above mentioned drugs and lipid lowering medications or changing the dosage of the drug, causing allergies or any discomfort with the intervention
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**
Actual sample size reached: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization was performed. The four blocks were selected and the men and women were divided equally into groups.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not 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
the central building of Shiraz University of Medical Science, Emam Hosein Ave., Zand Blvd., Shiraz Town
City
Shiraz
Province
Fars
Postal code
۱۴۳۳۶ - ۷۱۳۴۸
Approval date
2015-03-15, 1393/12/24
Ethics committee reference number
93-01-87-8898

Health conditions studied

1

Description of health condition studied
metabolic syndome
ICD-10 code
E88.9
ICD-10 code description
Metabolic disorder, unspecified

Primary outcomes

1

Description
Interleukin-6
Timepoint
At baseline (before intervention) and 7 weeks after flaxseed or sunflower oil consumption
Method of measurement
using ELIZA kit (IBL International GMBH, Germany).

2

Description
Total antioxidant capacity
Timepoint
At baseline (before intervention) and 7 weeks after flaxseed or sunflower oil consumption
Method of measurement
using ELISA kit (ZellBio GMBH German)

3

Description
Prothrombin Time
Timepoint
At baseline (before intervention) and 7 weeks after flaxseed or sunflower oil consumption
Method of measurement
The Prothrombin Time (PT) test was performed by adding the plasma to thromboplastin that converts prothrombin to thrombin. The mixture was then kept in a warm water bath at 37°C for one or two minutes. Afterwards, calcium chloride was added to the mixture and allow clotting to start. The test was timed from the addition of calcium chloride until the plasma clotted. This time was called PT.

4

Description
Partial thromboplastin time
Timepoint
At baseline (before intervention) and 7 weeks after flaxseed or sunflower oil consumption
Method of measurement
In order to carry out Partial Thromboplastin Time (PTT) test, decalcified blood was used to prevent clotting before the test. At first, the plasma was separated via centrifugation. After that, ionized calcium and activating substances were added to the plasma. These substances included kaolin (hydrated aluminum silicate) and cephalin. The PTT refers to the time it takes for a clot to form, measured in seconds

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Flax seed oil was prepared and packaged by a cold press machine. People add 25 cc of flaxseed oil daily to cold foods and consume for 7 weeks. A measuring spoon was provided to facilitate measurement by the participants.
Category
Other

2

Description
Control group: sunflower seed oil was prepared and packaged by a cold press machine. People add 25 cc of sunflower seed oil daily to cold foods and consume for 7 weeks. A measuring spoon was provided to facilitate measurement by the participants.
Category
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.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Ali Postforosh
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Zand St.
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Province
Fars
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Phone

+98 71 3230 5410

Email

president@sums.ac.ir

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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Atefeh Akrami

Position

Master of science

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Siavash Babajafari

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Atefeh Akrami

Position

Master of science

Latest degree

Master

Other areas of specialty/work

Nutrition

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Primary outcome data can be shared after unidentifiable.

When the data will become available and for how long

Access started in 1399

To whom data/document is available

Academics and industry people

Under which criteria data/document could be used

No special conditions

From where data/document is obtainable

Person in charge Atefeh Akrami Akramiat@sums.ac.ir

What processes are involved for a request to access data/document

One week after receiving the request by email

Comments