

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Effect of flaxseed oil supplementation on some inflammatory factors level in Patients with Coronary Artery Disease

Protocol summary

Summary

This randomized, double-blind, controlled clinical trial will be done on a total of 44 coronary artery disease (CAD) patients. Participants will be divided randomly into intervention and placebo groups. The CAD will be defined as presence of ≥ 1 stenotic coronary arteries with at least 50% stenosis confirmed by coronary angiography among subjects referring to Madani University hospital, Tabriz, Iran. The participants with 30-65 years old and BMI at the range of 25-35 will be included. Patients with other cardiovascular or chronic diseases will be excluded. To minimize the effect of confounders, matching will be applied for age, sex, BMI and any current anti-hyperlipidemic and anti-hypertensive medications. All the Subjects will be receiving a moderate calorie restricted dietary plan. They will be requested to consume 200 ml of milk prepared with 1.5% fat+ 2% flaxseed oil (containing 2 g alpha linolenic acid) or 1.5% fat milk for eight consecutive weeks. Food intake will be assessed using 3 days food record method at the beginning and end of the study. After 10-12 h fasting, 4 ml blood will be taken to evaluate primary outcomes. Informed consent form will be fulfilled prior to start of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017102811288N13**
Registration date: **2017-11-01, 1396/08/10**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-11-01, 1396/08/10

Registrant information

Name

Mohammad Alizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Tabriz University Of Medical Sciences

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of flaxseed oil supplementation on some inflammatory factors level in Patients with Coronary Artery Disease

Public title

Effect of flaxseed oil supplementation on some inflammatory factors level in Patients with Coronary Artery Disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Subjects with 30-65 years old; BMI equal 25-35 kg/m², angiographically confirmed coronary

artery disease with more than 50% stenosis of at least one of the major coronary vessels; Exclusion criteria: Heart failure (function class III and IV), Heart valve diseases; Diabetes dependent on insuline therapy or any other chronic disease; Consumption of any immunosuppressive drugs; Antioxidant and/or vitamin supplements; Fish oil or (n-3) fatty acid supplements; Weight loss drugs or weight loss surgery; Smoking and drug users; Pregnant and lactating women; Those with Lactase deficiency (milk intolerance)

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Tabriz University Of Medical Sciences

Street address

Golghasht St,

City

Tabriz

Postal code

Approval date

2017-09-18, 1396/06/27

Ethics committee reference number

IR.TBZMED.REC.1396.613

Health conditions studied

1

Description of health condition studied

Coronary Artery Disease

ICD-10 code

170

ICD-10 code description

Atherosclerosis

Primary outcomes

1

Description

Serum Levels Of MMP-9

Timepoint

Pre And Post Intervention

Method of measurement

ELISA Kit

2

Description

Serum Levels Of MCP-1

Timepoint

Pre And Post Intervention

Method of measurement

ELISA Kit

Secondary outcomes

1

Description

Energy And Macronutrient Levels

Timepoint

Pre And Post Intervention

Method of measurement

Food Record Questionnaire

2

Description

Physical Activity Level

Timepoint

Pre And Post Intervention

Method of measurement

International Physical Activity Questionnaire

Intervention groups

1

Description

Intervention Group|: 200 ml Of Milk Prepared With 1.5% Fat+ 2 % Flaxseed Oil (containing 2 g alpha linolenic acid)/day For 2 Months

Category

Lifestyle

2

Description

Control Group: 200 ml Of milk contained 1.5% fat/ Day For 2 Mounths

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Hospital, Tabriz

Full name of responsible person

Dr. Mohammad Alizadeh

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Office Of The Vice Chancellor For Research Of Tabriz
University Of Medical Sciences

Full name of responsible person

Dr. Rashidi

Street address

Vice Chancellor for Research No 2 Central Building,
Tabriz University of Medical Sciences, Daneshgah
Street, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Office Of The Vice Chancellor For Research Of Tabriz
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

Faculty Of Nutrition And Food Science, Tabriz
University Of Medical Sciences

Full name of responsible person

Sevda Saleh- Ghadimi

Position

Ph.D. Candidate Of Nutrition Science

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Faculty Of Nutrition And Food Science, Tabriz
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Person responsible for updating data

Contact

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Full name of responsible person

Sevda Saleh-Ghadimi

Position

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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