Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Name of organization / entity
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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
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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