Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of flaxseed oil supplementation on Omentin, Chemerin and Thromboxane B2 levels in Patients with Coronary Artery Disease

Protocol summary

Study aim

1- Determination and comparison of the effect of flaxseed oil and placebo on serum Omentin in patients with coronary artery disease 2- Determination and comparison of the effect of flaxseed oil and placebo on serum Chemerin in patients with coronary artery disease 3- Determination and comparison of the effect of flaxseed oil and placebo on serum Thromboxan B2 in patients with coronary artery stenosis

Design

In this double blind randomized trial (randomized randomized trial), 44 patients with coronary artery stenosis (coronary angiography confirmation) will be included in the study based on inclusion criteria and no admission for 2 months.

Settings and conduct

Among those who are referring to the Shahid Madani Hospital in Tabriz, qualified individuals are given a brief explanation for the study. People who agree to participate in the study are asked to start taking either new medication or Investigate the onset of any side effects as a result of the use of flaxseed oil supplementation. To minimize the effects of confounding factors, individuals are randomly assigned to complement and placebo groups for age, sex, BMI, and received drugs (lipid lowering and blood pressure). The researchers and participants of the study were blinded in this study. The blindness is such that the manufacturer of the plant has provided a code for supplementation and a code for the placebo, and this code is maintained by the expert responsible for the manufacturer's factory until the end of the study.

Participants/Inclusion and exclusion criteria

Entry Requirements: 1) age range of 60-30 years 2) BMI ranges from 35 to 25 kg / m 2 3) Proof of stenosis of 50% ≤ minimum in one of the major coronary arteries through angiography 4) willingness and ability to cooperate in the plan Conditions for not admitting to study: 1) Myocardial Infarction, Cardiac Functional Cardiac Disorders 3 and 4 (FC III, IV), Cardiac valve disease Diabetes and any other chronic inflammatory disease 2) Use of suppressive drugs or vitamin supplements and antioxidants, fish oil or any type of supplementation of omega-3 3) Use more than two servings of fish per week 4) Use of weight loss medications or weight loss surgery 5) Smoking or substance abuse 6) Pregnant or breastfeeding

Intervention groups

The intervention group received 200 cc milk with 2.5% fat, prepared with flaxseed oil (containing 2 g of alpha linolenic acid) and the placebo group received the same amount of non-fat sterilized milk for 2 months and the fat in both groups By diet design, each person will be adjusted.

Main outcome variables

Omentin, Chemerin, Thromboxane B2

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121028011288N9**
Registration date: **2018-01-22, 1396/11/02**
Registration timing: **retrospective**

Last update: **2018-01-22, 1396/11/02**
Update count: **0**

Registration date

2018-01-22, 1396/11/02

Registrant information

Name

Mohammad Alizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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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 Omentin, Chemerin and Thromboxane B2 levels in Patients with Coronary Artery Disease

Public title
Effect of flaxseed oil supplementation on Omentin, Chemerin and Thromboxane B2 levels in Patients with Coronary Artery Disease
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age ranges from 30 years to 60 years BMI in the range of 35- 25 kg / m2 Proof of stenosis of 50% ≤ minimum in one of the major coronary arteries through angiography Desire and ability to cooperate in the project
Exclusion criteria:
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: Block randomization
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants and main investigators have been blinded.
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
Province
East Azarbaijan
Postal code
5145666691
Approval date
2017-10-11, 1396/07/19
Ethics committee reference number
IR.TBZMED.REC.1396.615

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
Omentin
Timepoint
Pre And Post Intervention
Method of measurement
ELISA Kit

2

Description
Chemerin
Timepoint
Pre And Post Intervention
Method of measurement
ELISA Kit

3

Description
Thromboxane B2
Timepoint
Pre And Post Intervention

Method of measurement
ELISA Kit

Secondary outcomes

1

Description
Body fat percentage
Timepoint
Pre And Post Intervention
Method of measurement
BIA

2

Description
Fat Free Mass
Timepoint
Pre And Post Intervention
Method of measurement
BIA

3

Description
Quality of Life
Timepoint
Pre Intervention
Method of measurement
health promoting life style profile (HPLP II) 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
Shahid Madani Hospital, Golbad Street, Tabriz town
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5145666691
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Of Tabriz University Of Medical Sciences
Full name of responsible person
Dr. Mohammadreza Rashidi
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Golgasht St
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Of Tabriz 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
Faculty Of Nutrition And Food Science, Tabriz University Of Medical Sciences
Full name of responsible person
Zahra Mollarasouli
Position
M.Sc student Of Nutrition Science
Latest degree

Bachelor

Other areas of specialty/work

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Full name of responsible person

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MD, PhD

Latest degree

Ph.D.

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Person responsible for updating data

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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

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

Informed Consent Form

Yes - There is 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Demographic and primary outcomes data of participants

When the data will become available and for how long

Accessibility to data is possible 1 year after publication.

To whom data/document is available

Researchers who are working in academic institutes.

Under which criteria data/document could be used

Only observation of documents is allowed; Analysis and use of data is not possible.

From where data/document is obtainable

Dr. Mohammad Alizadeh, Faculty of Nutrition and Food Sciences, Tabriz University of Medical Sciences, 09141894102, mdalizadeh@tbzmed.ac.ir 2. Zahra Mollarasouli , Faculty of Nutrition and Food Sciences, Tabriz University of Medical Sciences, 09370258717, zrasouli92@yahoo.com

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

The applicator can send a request to the person responsible for the study by email and within 20 days the document will be sent to the requesting person.

Comments