Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of flaxseed consumption on inflammation and vascular endothelial function markers in coronary artery disease patients

Protocol summary

Summary

Objective: To examine the effect of flaxseed consumption on inflammation and vascular endothelial function markers in patients with coronary artery disease Design: This study is a single center, not blinded, randomized clinical trial with two parallel groups in third phase. In this study, 60 non smoker patients with coronary artery disease referred for angioplasty in Rajaee hospital, will be randomized into two groups, falxseed (30 gram of flaxseed per day) or placebo (1 gram of wheat fiber) for 3 months. Vascular endothelial function will be evaluated through measurement of flow mediated dilatation (FMD) in brachial artery via ultrasound sonography. Fasting blood sample will be taken at the baseline and the end of study to measure plasma level of C-reactive protein and inflammatory cytokines.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017040328742N2**
Registration date: **2017-06-13, 1396/03/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-13, 1396/03/23

Registrant information

Name

Javad Nasrollahzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2236 0656

Email address

jnasrolah@razi.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of flaxseed consumption on inflammation and vascular endothelial function markers in coronary artery disease patients

Public title

Effect of flaxseed in patients with heart disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1) coronary artery disease patients (more than 50% blockage in coronary arteries) needed angioplasty with stent 2) willing to participation in the study Exclusion Criteria: 1) cigarette Smoking 2) continuous consumption of any antioxidant supplement such as vitamin E, vitamin C and Selenium in last month 3) consumption of flaxseed or any omega-3 supplement at the beginning of the study 4) ādvanced renal disease 5) unwillingness to continuance 6) any change in disease treatment plan such as change in type and dose of lipid

lowering drugs or surgical operation

Age

From **20 years** old to **75 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

Used

Assignment

Parallel

Other design features

Type of randomization: simple (complete randomness of the assignment of a subject to a particular group) by an random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Rajaei Cardiovascular, Medical & Research Center

Street address

Niyayesh Conjunction, Valiasr Street, Tehran

City

Tehran

Postal code

Approval date

2016-12-07, 1395/09/17

Ethics committee reference number

rhc.ac.ir.rec.1395.30

Health conditions studied

1

Description of health condition studied

Coronary heart disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes

1

Description

Flow Mediated Dilatation (FMD)

Timepoint

Baseline and the end of the study

Method of measurement

Ultrasound Sonography

Secondary outcomes

1

Description

Blood inflammatory cytokines

Timepoint

At baseline and the end of the study

Method of measurement

ELISA

Intervention groups

1

Description

Control: Daily consumption of one capsule containing 1 gr wheat fiber for 3 months

Category

Lifestyle

2

Description

Intervention: Daily consumption of 30 gr flaxseed for 3 months

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaee Cardiovascular, Medical & Research Center

Full name of responsible person

Street address

Niyayesh Conjunction, Valiasr Street, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti

University of Medical Sciences

Full name of responsible person

Dr Morteza Abdollahi

Street address

No. 46, Hafezi St, Farahzadi Blvd, Qods Town, Tehran

City

Tehran

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, Shahid Beheshti 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 Sciences, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nafiseh Khandouzi

Position

Ph.D. Student

Other areas of specialty/work

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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