Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

A comparison between the effects of flaxseed oil and fish oil supplementation on cardiovascular health in type 2 diabetic patients with coronary heart disease

Protocol summary

Study aim

Objective: The aim of this study is to compare the effects of flaxseed oil and fish oil supplementation on cardiovascular health in type 2 diabetic patients with coronary heart disease.

Design

Study design: Randomized double-blind placebo-controlled trial. To decrease potential confounding effects, all participants will have stratified randomization according to BMI (<25 and ≥25 kg/m2) and age (<65 and ≥65 y). Then, participants in each block will be randomly allocated into three groups to take either supplements or placebo. Randomization will be done by the use of computer software.

Settings and conduct

Among patients with CHD referred to cardiology Clinic affiliated to Kashan University of Medical Sciences, 90 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. At the beginning and the end of the intervention: 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Subjects aged 40-100 years diagnosed with type 2 diabetes and coronary heart disease. Exclusion Criteria: Individuals consuming omega-3 supplements within the last 3 months, having an acute myocardial infarction or cardiac surgery within the past 3 months.

Intervention groups

Intervention group 1: Omega-3 fatty acid (flaxseed oil) pearl, 1000 mg, BID, for 3 months orally. Intervention group 2: Omega-3 fatty acid (fish oil) pearl, 1000 mg, BID, for 3 months orally. control group: placebo pearl, 1000 mg, BID, for 3 months orally.

Main outcome variables

Outcomes: Insulin resistance (primary outcomes) and lipid profile, weight, BMI, biomarkers of inflammation and oxidative stress (secondary outcomes) will be quantified at study baseline and end-of-trial

General information

Reason for update

The revisions were accordance with the original approved proposal and with coordination with Vice Chancellor of Research at the University.

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020412438N22**
Registration date: **2017-04-21, 1396/02/01**
Registration timing: **retrospective**

Last update: **2020-12-02, 1399/09/12**
Update count: **2**

Registration date

2017-04-21, 1396/02/01

Registrant information

Name
Mohsen Taghizadeh
Name of organization / entity
Kashan University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Barij Research Center of Medicinal Herbs

Expected recruitment start date
2017-01-01, 1395/10/12
Expected recruitment end date
2017-01-30, 1395/11/11
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparison between the effects of flaxseed oil and fish oil supplementation on cardiovascular health in type 2 diabetic patients with coronary heart disease

Public title
Effect of Omega-3 fatty acid on patients with coronary heart disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion Criteria: Subjects aged 40-100 years Patients diagnosed with type 2 diabetes and coronary heart disease
Exclusion criteria:
Exclusion Criteria: Individuals consuming omega-3 supplements within the last 3 months having an acute myocardial infarction or cardiac surgery within the past 3 months
Age
From **40 years** old to **100 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
To decrease potential confounding effects, all participants will have stratified randomization according to BMI (<25 and ≥25 kg/m2) and age (<65 and ≥65 y). Then, participants in each block will be randomly allocated into three groups to take either supplements or placebo. Randomization will be done by the use of computer software.
Blinding (investigator's opinion)
Double blinded
Blinding description
Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the cardiology clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of supplements
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kashan University of Medical Sciences
Street address
Kashan University Of Medical Sciences, Kashan
City
Kashan
Province
Isfehan
Postal code
1771844351
Approval date
2016-11-16, 1395/08/26
Ethics committee reference number
IR.KAUMS.REC.1395.84

Health conditions studied

1

Description of health condition studied
Coronary Heart Disease
ICD-10 code
I25.9
ICD-10 code description
Chronic ischemic heart disease, unspecified

Primary outcomes

1

Description
Insulin resistance
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Calculation using HOMA formula

Secondary outcomes

1

Description
Insulin
Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

2

Description

Total cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

3

Description

Triglycerides

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

4

Description

HDL

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

5

Description

Hs-CRP

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

6

Description

Nitric oxide

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

7

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

8

Description

Glutathione

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

9

Description

Total antioxidant capacity

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

10

Description

Weight

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

scale

11

Description

BMI

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Formula

Intervention groups

1

Description

Intervention group: Omega-3 fatty acid (flaxseed oil) pearl, 1000 mg, BID, for 3 months orally.

Category

Treatment - Drugs

2

Description

Intervention group: Omega-3 fatty acid (fish oil) pearl, 1000 mg, BID, for 3 months orally.

Category

Treatment - Drugs

3

Description

control group: placebo pearl, 1000 mg, BID, for 3 months orally.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti hospital of Kashan

Full name of responsible person

Dr Fariba Raygan

Street address

Ghotbe Ravandi Boulevard, Kashan

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1771844351

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raygan.fariba2@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamidreza Banafsheh

Street address

Kashan Mashhad Ardehal Road, KM44

City

Kashan

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Isfehan

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1771844351

Phone

+98 31 5554 2999

Email

Banafsheh.hr@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

Nutritionist

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

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