

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial of the effect of combined omega-3 and vitamin D supplementation compared with the placebo on carotid intima-media thickness and metabolic profiles in type 2 diabetic patients with coronary heart disease

Protocol summary

Study aim

The aim of this study is to determine the effects of combined omega-3 and vitamin D supplementation on carotid intima-media thickness (CIMT) and metabolic profiles in type 2 diabetic patients with coronary heart disease (CHD).

Design

Randomized double-blind placebo-controlled trial.

Settings and conduct

Among patients with coronary heart disease referred to Cardiology Clinic affiliated to Kashan University of Medical Sciences, 74 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 the beginning and the end of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Individuals aged 45-85 years diagnosed with type 2 diabetes, CHD and vitamin D-deficient.
Exclusion criteria: Consuming vitamin D supplements and omega-3 fatty acids within the last 3 months, experiencing an acute myocardial infarction or cardiac surgery within the past 3 months, renal or hepatic disorder.

Intervention groups

Intervention group: 2000 mg omega-3 daily (Barij Essence, Kashan, Iran) and 50000 IU vitamin D every 2 weeks (Zahravi, Tabriz, Iran), for 24 weeks orally. Control group: Placebo capsule (Barij Essence, Kashan, Iran), every 2 weeks for 24 weeks orally.

Main outcome variables

Carotid intima-media thickness (primary outcome) and metabolic profiles (secondary outcomes) will

General information

Reason for update

Due to an error, the request for an update in our website has conducted after paper published. However, the revisions were accordance with coordination with Vice Chancellor of Research at the University.

Acronym

IRCT registration information

IRCT registration number: **IRCT2017090133941N15**

Registration date: **2017-11-01, 1396/08/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-05, 1399/05/15**

Update count: **2**

Registration date

2017-11-01, 1396/08/10

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5546 3378

Email address

ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2017-11-01, 1396/08/10

Expected recruitment end date

2017-11-14, 1396/08/23

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of combined omega-3 and vitamin D supplementation compared with the placebo on carotid intima-media thickness and metabolic profiles in type 2 diabetic patients with coronary heart disease

Public title
Effect of combined omega-3 and vitamin D supplementation in treatment of coronary heart disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Subjects aged 45-85 years Diagnosed with type 2 diabetes and coronary heart disease Vitamin D-deficient
Exclusion criteria:
Consuming vitamin D supplements and omega-3 fatty acids within the last 3 months Experiencing an acute myocardial infarction or cardiac surgery within the past 3 months Renal or hepatic disorder

Age
From **45 years** old to **85 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
To decrease potential confounding effects, all participants will have stratified randomization according to BMI and age. Then, participants in each block will be randomly allocated into two treatment groups to take either omega-3 and vitamin D supplement or placebo. Randomization will be done by the use of Stat Trek software. Participants, investigators or the assessors of the outcomes are also unaware of the study groups. <https://stattrek.com/statistics/random-number-generator.aspx>

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 clinics affiliated with Kashan University of Medical Sciences, who is not involved in the trial and not aware of random

sequences, will be assigned the participants to the numbered bottles of capsules. Supplements and placebo are in the same packaging at the Barij Essence pharmaceutical company. Only the code is written on the packages. Patients and researcher do not know the type of drug and after analyzing the data, packet codes are decoded.

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

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Approval date

2017-10-12, 1396/07/20

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1396.79

Health conditions studied

1

Description of health condition studied

Coronary Heart Disease

ICD-10 code

I25.9

ICD-10 code description

Chronic ischaemic heart disease, unspecified

Primary outcomes

1

Description

Mean left CIMT

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Sonography

2

Description

Maximum left CIMT

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Sonography

3

Description

Mean right CIMT

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Sonography

4

Description

Maximum right CIMT

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Sonography

Secondary outcomes

1

Description

Insulin

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Elisa kit

2

Description

Insulin resistance

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Calculation using HOMA formula

3

Description

Total cholesterol

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Enzymatic kit

4

Description

Triglycerides

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Enzymatic kit

5

Description

HDL

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Enzymatic kit

6

Description

Hs-CRP

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Elisa kit

7

Description

Nitric oxide

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Spectrophotometry

8

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Spectrophotometry

9

Description

Glutathione

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Spectrophotometry

10

Description

Total antioxidant capacity

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Spectrophotometry

Intervention groups**1****Description**

Intervention group: 2000 mg omega-3 daily (Barij Essence, Kashan, Iran) and 50000 IU vitamin D every 2 weeks (Zahravi, Tabriz, Iran), for 24 weeks orally.

Category

Treatment - Drugs

2**Description**

Control group: Placebo capsule (Barij Essence, Kashan, Iran), every 2 weeks for 24 weeks orally.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Cardiology Clinic affiliated to Kashan University of Medical Sciences

Full name of responsible person

Fariba Raygan

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Shahid Rajaee Avenue, Kashan

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Kashan

Province

Isfahan

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8115187159

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+98 31 5546 3378

Email

asemi_r@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

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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

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

Ph.D of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

Zatollah Asemi

Position

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Latest degree

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Web page address**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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Person responsible for updating data**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

Ph.D of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition