Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 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

Isfehan

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
Street address
Shahid Rajaee Avenue, Kashan
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Isfehan
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8115187159
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+98 31 5546 3378
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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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Ghotbe Ravandi Boulevard, Kashan
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hamidi_gh@kaums.ac.ir
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
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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
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