

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effects of long-term vitamin D supplementation compared with the placebo on carotid intima media thickness (CIMT) and metabolic profiles among type 2 diabetes patients with coronary heart disease

Protocol summary

Study aim

The aim of this study is to determine the effects of long-term vitamin D supplementation on carotid intima media thickness (CIMT) and metabolic profiles among type 2 diabetes patients with coronary heart disease (CHD).

Design

Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers.

Settings and conduct

Population and sample size: 60 type 2 diabetes patients with CHD eligible and referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Individuals aged 40-85 years diagnosed with type 2 diabetes and CHD will be included in this study. Exclusion criteria: Consuming vitamin D supplements within the past 3 months, having an acute myocardial infarction within the past 3 months, having cardiac surgery within the past 3 months, important hepatic failure and adequate vitamin D status.

Intervention groups

Intervention: Patients will be assigned to receive either 50000 IU vitamin D supplements every two weeks (intervention group: n=30) or placebo (control group: n=30). CIMT will be determined at baseline and after 24-wk intervention.

Main outcome variables

Outcomes: Biomarkers of insulin metabolism (primary outcomes), and lipid and metabolic profiles (secondary outcomes) will be quantified at the study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201510315623N56**

Registration date: **2015-12-02, 1394/09/11**

Registration timing: **retrospective**

Last update: **2019-09-24, 1398/07/02**

Update count: **1**

Registration date

2015-12-02, 1394/09/11

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1534 3570

Email address

asemi_z@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2015-10-29, 1394/08/07

Expected recruitment end date

2015-11-06, 1394/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Effects of long-term vitamin D supplementation compared with the placebo on carotid intima media thickness (CIMT) and metabolic profiles among type 2 diabetes patients with coronary heart disease

Public title
Effect of supplementation in treatment of Coronary Heart Disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Subjects aged 40-85 years Diagnosed with type 2 diabetes and coronary heart disease

Exclusion criteria:
Consuming vitamin D supplements within the past 3 months Having an acute myocardial infarction within the past 3 months Having cardiac surgery within the past 3 months Important hepatic failure Adequate vitamin D status

Age
From **40 years** old to **85 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take vitamin D supplements (n = 30) or placebo (n = 30). Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants, investigators or the assessors of the outcomes are unaware of the study groups.

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

City
Kashan

Province
Isfahan

Postal code
81151-87159

Approval date
2015-10-28, 1394/08/06

Ethics committee reference number
IR.KAUMS.REC.1394.91

Health conditions studied

1

Description of health condition studied
Coronary Heart Disease

ICD-10 code
I25.9

ICD-10 code description
Ischaemic heart disease (chronic) NOS

Primary 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
Questionnaire

Secondary outcomes

1

Description
Fasting blood sugar

Timepoint

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

Method of measurement

Enzymatic kit

2

Description

Triglycerides

Timepoint

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

Method of measurement

Enzymatic kit

3

Description

HDL-cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

4

Description

Total cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

5

Description

Hs-CRP

Timepoint

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

Method of measurement

Elisa kit

6

Description

Nitric oxide

Timepoint

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

Method of measurement

Spectrophotometry

7

Description

Malondialdehyde

Timepoint

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

Method of measurement

Spectrophotometry

8

Description

Glutathione

Timepoint

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

Method of measurement

Spectrophotometry

9

Description

Total antioxidant capacity

Timepoint

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

Method of measurement

Spectrophotometry

10

Description

Carotid intima media thickness

Timepoint

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

Method of measurement

Sonography

Intervention groups

1

Description

Control group: Placebo capsule, every 2 weeks, for 24 weeks orally.

Category

Treatment - Drugs

2

Description

Intervention group: Vitamin D capsule, 50000 IU, every 2 weeks, for 24 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Naghavi Clinic

Full name of responsible person

Zatollah Asemi

Street address

Shahid Rajaei Avenue, Kashan

City

Kashan
Province
Isfahan
Postal code
81151-87159
Phone
+98 31 5546 3378
Email
asemi_r@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Kashan University of
Medical Sciences
Full name of responsible person
Gholamali Hamidi
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfahan
Postal code
81151-87159
Phone
+98 31 5554 2999
Email
research@kaums.ac.ir

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, 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
Nutrition PhD
Latest degree

Ph.D.
Other areas of specialty/work
Nutrition
Street address
Bolvare Ghotbe Ravandi, Kashan
City
Kashan
Province
Isfahan
Postal code
81151-87159
Phone
+98 31 5546 3378
Email
asemi_z@kaums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
PhD of Nutrition
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfahan
Postal code
81151-87159
Phone
+98 31 5546 3378
Fax
Email
asemi_z@kaums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
PhD of Nutrition
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan

Province

Isfehan

Postal code

81151-87159

Phone

+98 31 5546 3378

Fax**Email**

asemi_z@kaums.ac.ir

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

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