

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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)

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+98 36 1534 3570

Email address

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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 Rajaee Avenue, Kashan
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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
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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
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Person responsible for updating data

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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