Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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: Invituals 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 (secondry 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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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

Isfehan

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
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Person responsible for updating data

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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