Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effects of calcium, vitamins D and K co-supplementation on insulin resistance, inflammatory factors and biomarkers of oxidative stress in Coronary Heart Disease

Protocol summary

Study aim

The aim of this study is to determine the effects of combined calcium, vitamins D and K supplementation on metabolic profiles, inflammatory factors and biomarkers of oxidative stress among type 2 diabetes patients with coronary heart disease (CVD).

Design

In this parallel double-blind randomized controlled clinical trial, patients with type 2 diabetes and CVD will be included in this study. Patients will be assigned to receive either combined calcium, vitamins D and K supplements or placebo. Fasting blood samples will be taken at baseline and after 12-wk intervention to measure biochemical factors.

Settings and conduct

This study will be carried out at cardiology clinic affiliated to Kashan University of Medical Sciences (KUMS), Kashan, Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria were as follows: overweight patients (BMI≥25) with T2DM, aged 40-85 years old with CHD condition. Exclusion criteria were consuming vitamin D, K and calcium supplements within the last 3 months, having an acute myocardial infarction within the past 3 months, a cardiac surgery within the past 3 months and a major renal or liver failure.

Intervention groups

Patients will be assigned to receive either combined calcium, vitamins D and K supplements (intervention group: n=33) or placebo (control group: n=33).

Main outcome variables

Fasting plasma glucose (FPG), serum insulin, lipid profiles, inflammatory factors and biomarkers of oxidative stress will be measured at baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201506185623N45**
Registration date: **2015-06-22, 1394/04/01**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-14, 1398/06/23**
Update count: **1**

Registration date

2015-06-22, 1394/04/01

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

Kashan University of Medical Sciences

Expected recruitment start date

2015-06-02, 1394/03/12

Expected recruitment end date

2015-07-09, 1394/04/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effects of calcium, vitamins D and K co-supplementation on insulin resistance, inflammatory factors and biomarkers of oxidative stress in Coronary Heart Disease

Public title
Effect of supplementation in treatment of Coronary Heart Disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Overweight patients (BMI≥25) with T2DM Aged 40-85 years old with CHD

Exclusion criteria:
Consuming vitamin D, K and calcium supplements within the last 3 months Having an acute myocardial infarction within the past 3 months Having a cardiac surgery within the past 3 months A major renal or liver failure

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: **66**

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 either vitamin D, K and calcium supplements (n = 33) or placebo (n = 33). Randomization will be done by the use of computer-generated random numbers.

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 clinic affiliated to Kashan University of Medical Sciences (KUMS), Kashan, Iran, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kashan University of Medical Sciences

Street address
Bolvare Ghotbe Ravandi, Kashan

City
Kashan

Province
Isfehan

Postal code
81151-87159

Approval date
2015-06-01, 1394/03/11

Ethics committee reference number
IR.Kaums.REC.1394.32

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
Carotid intima media thickness

Timepoint
Baseline and End-of-trial

Method of measurement
Sonography

Secondary outcomes

1

Description
Insulin

Timepoint
At the beginning of the study and after 12 weeks of intervention

Method of measurement
Elisa kit

2

Description
Insulin resistance

Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Calculation using HOMA formula

3

Description
Total cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
Triglycerides
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

5

Description
HDL
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

6

Description
Hs-CRP
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

7

Description
Nitric oxide
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

8

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

9

Description
Glutathione
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

10

Description
Total antioxidant capacity
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

Intervention groups

1

Description
Intervention group: Combined 200 IU vitamin D, 90 µg vitamin K2 and 500 mg calcium supplements daily twice for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo tablet, daily, twice for 12 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Naghavi Clinic
Full name of responsible person
Zatollah Asemi
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Sponsors / Funding sources

1

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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
Nutritionist
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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