

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Aug 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 ($BMI \geq 25$) 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

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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 $\geq$ 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

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Bolvare Ghotbe Ravandi, Kashan

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Isfahan

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

Sponsor

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Full name of responsible person

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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

Latest degree

Ph.D.

Other areas of specialty/work

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

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