Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Effects of selenium 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 selenium supplementation on metabolic profiles, inflammatory factors and biomarkers of oxidative stress in Coronary Heart Disease (CVD).

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 subjects with CVD eligible and referred to Outpatient Cardiology 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: Smokers, consuming selenium or antioxidant supplements within the past 3 months, having an acute myocardial infarction within the past 3 months, having cardiac surgery within the past 3 months and a major renal or liver failure.

Intervention groups

Intervention: Patients will be assigned to receive either 200 µg selenium supplements (intervention group: n=30) or placebo (control group: n=30). Fasting blood samples will be taken at baseline and after 8-wk intervention to measure metabolic profiles, inflammatory factor and biomarkers of oxidative stress. Start and End Date of Intervention: 8 weeks

Main outcome variables

Outcomes: Biomarkers of insulin metabolism and hs-CRP (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

Due to an error, the request for an update in our website was conducted after paper published. However, the revisions were accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

Acronym

IRCT registration information

IRCT registration number: **IRCT201407015623N22**
Registration date: **2014-07-21, 1393/04/30**
Registration timing: **retrospective**

Last update: **2019-10-17, 1398/07/25**
Update count: **1**

Registration date

2014-07-21, 1393/04/30

Registrant information

Name
Zatollah Asemi
Name of organization / entity
Kashan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2014-07-07, 1393/04/16

Expected recruitment end date

2014-07-21, 1393/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of selenium 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:

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

Exclusion criteria:

Smokers Consuming selenium or antioxidant supplements within the past 3 months Having an acute myocardial infarction within the past 3 months Having 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: **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 selenium 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

Kashan University of Medical Sciences

Street address

Bolvare Ghotbe Ravandi, Kashan

City

Kashan

Province

Isfehan

Postal code

81151-87159

Approval date

2014-07-06, 1393/04/15

Ethics committee reference number

29/5/1/1683/پ

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

Baseline and End-of-trial

Method of measurement

Elisa kit

2

Description

Insulin resistance

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa kit

3

Description

hs-CRP

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa kit

4

Description
QUICKI
Timepoint
Baseline and End-of-trial
Method of measurement
Elisa kit

Secondary outcomes

1

Description
HDL
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

2

Description
Total Antioxidant Capacity
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Spectrophotometry

3

Description
Triglycerides
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
Total cholesterol
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

5

Description
Glutathione
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Spectrophotometry

6

Description
Nitric oxide
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Spectrophotometry

7

Description
VLDL
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

8

Description
LDL
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

9

Description
FPG
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

10

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Spectrophotometry

Intervention groups

1

Description
Intervention group: Selenium tablet, 200 µg, daily, for 8 weeks orally.
Category
Treatment - Drugs

2

Description

Control group: Placebo tablet, daily, for 8 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Outpatient Cardiology 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

Kashan University of Medical Sciences

Full name of responsible person

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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

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

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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