Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Clinical trial of the effect of combined probiotic and selenium supplementation compared with the placebo on metabolic profiles in type 2 diabetic patients with coronary heart disease

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of combined probiotic and selenium supplementation on metabolic profiles in type 2 diabetic patients with coronary heart disease (CHD).

Design

Study design: Randomized double-blind placebo-controlled trial. Randomization will be done by the use of computer-generated random numbers. Patients will be assigned into two groups to receive combined probiotic and selenium supplements (n=30) or placebo (n=30).

Settings and conduct

Among patients with CHD referred to Naghavi outpatient Clinic affiliated to Kashan University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. At the beginning and the end of the intervention: 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Individuals aged 45-85 years diagnosed with type 2 diabetes and CHD will be included in this study. Exclusion criteria: Selenium, probiotic and/or synbiotic consumption within the last 3 months, patients with thyroid disorders, severe renal insufficiency and hepatic failure, experiencing an acute myocardial infarction and cardiac surgery within the past 3 months .

Intervention groups

Intervention group: Combined probiotic, including 2×109 Lactobacillus acidophilus, 2×109 Bifidobacterium bifidum, 2×109 Lactobacillus reuteri, 2×109 Lactobacillus fermentum daily, and selenium supplements (Webber Naturals, Coquitlam, Canada), 200 µg, daily, for 12 weeks orally.

Main outcome variables

Outcomes: Insulin resistance (primary outcomes) and other metabolic profiles (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

correction

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N28**
Registration date: **2018-01-18, 1396/10/28**
Registration timing: **retrospective**

Last update: **2019-10-28, 1398/08/06**
Update count: **2**

Registration date

2018-01-18, 1396/10/28

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5546 3378

Email address

ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-29, 1396/10/08

Expected recruitment end date

2018-01-15, 1396/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of combined probiotic and selenium supplementation compared with the placebo on metabolic profiles in type 2 diabetic patients with coronary heart disease

Public title

Effect of combined probiotic and selenium supplementation in treatment of coronary heart disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion Criteria: patients diagnosed with type 2 diabetes and coronary heart disease. Individuals aged 45-85 years.

Exclusion criteria:

Exclusion Criteria: Selenium, probiotic and/or synbiotic consumption within the last 3 months Patients with thyroid disorders Severe renal insufficiency and hepatic failure Experiencing an acute myocardial infarction and cardiac surgery within the past 3 months

Age

From **45 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 first, all participants were categorized according to age and pre-intervention BMI. Then, patients were randomly allocated into two groups to take either supplements or placebo. 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

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

8115187159

Approval date

2017-12-28, 1396/10/07

Ethics committee reference number

IR.KAUMS.REC.1396.62

Health conditions studied

1

Description of health condition studied

Coronary Heart Disease

ICD-10 code

I25.9

ICD-10 code description

Chronic ischemic heart disease, unspecified

Primary outcomes

1

Description

Insulin resistance

Timepoint

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

Method of measurement

Calculation using HOMA formula

Secondary outcomes

1

Description

Total cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

2

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

3

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

4

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

5

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

6

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

7

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

8

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

9

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

10

Description
Beck Depression Inventory
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

11

Description
Beck Anxiety Inventory
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

12

Description
Pittsburgh Sleep Quality Index
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

13

Description
Systolic blood pressure
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Manometer

14

Description
Diastolic blood pressure
Timepoint
At the beginning of the study and after 12 weeks of intervention

Method of measurement
Manometer

Intervention groups

1

Description
Intervention group: Combined probiotic, including 2×109 Lactobacillus acidophilus, 2×109 Bifidobacterium bifidum, 2×109 Lactobacillus reuteri, 2×109 Lactobacillus fermentum daily, and selenium supplements (Webber Naturals, Coquitlam, Canada), 200 µg, daily, for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo (Barij essence, Kashan, Iran), daily, for 12 weeks orally.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Naghavi outpatient Cardiology Clinic
Full name of responsible person
Zatollah Asemi
Street address
Shahid Rajaee Avenue, Kashan
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Isfehan
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Email
asemi_z@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
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hamidi_gh@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
Nutritionist
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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Position
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Latest degree
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Other areas of specialty/work
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8115187159
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asemi_z@kaums.ac.ir
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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