Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Clinical trial of the effect of probiotic 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 probiotic 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 probiotic supplement (n=30) or placebo (n=30).

Settings and conduct

Among patients with type 2 diabetes and coronary heart disease referred to Naghavi Cardiology 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.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with type 2 diabetes and coronary heart disease aged 40 to 85 years. Exclusion criteria: Consuming probiotic and/or synbiotic within three months prior to the intervention, taking prebiotic, antioxidant and/or anti-inflammatory supplements such as vitamin E, vitamin C and omega-3 fatty acids, taking antibiotics, having an acute myocardial infarction and a cardiac surgery in the past three months, renal or hepatic failure.

Intervention groups

Intervention group: Probiotic supplements containing three strains of Lactobacillus acidophilus (2×109 CFU/g), Lactobacillus casei (2×109 CFU/g) and Bifidobacterium bifidum (2×109 CFU/g), daily, for 12 weeks orally. Control group: Placebo capsule (Barij essence, Kashan, Iran), daily, for 12 weeks orally.

Main outcome variables

Outcomes: Markers of insulin metabolism (primary outcomes) and lipid profiles, biomarkers of inflammation and oxidative stress (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

correction

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082733941N5**
Registration date: **2017-09-07, 1396/06/16**
Registration timing: **retrospective**

Last update: **2019-10-11, 1398/07/19**
Update count: **3**

Registration date

2017-09-07, 1396/06/16

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2017-08-17, 1396/05/26

Expected recruitment end date
2017-09-02, 1396/06/11
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

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

Public title
Effect of probiotic supplementation in treatment of coronary heart disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Subjects aged 40-85 years Patients diagnosed with type 2 diabetes and coronary heart disease
Exclusion criteria:
Consuming probiotic and/or synbiotic within three months prior to the intervention Taking prebiotic, antioxidant and/or anti-inflammatory supplements such as vitamin E, vitamin C and omega-3 fatty acids Taking antibiotics Having an acute myocardial infarction and a cardiac surgery in the past three months Renal or hepatic failure
Age
From **40 years** old to **85 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
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
2017-08-16, 1396/05/25
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1396.37

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
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

Secondary outcomes

1

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

2

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

10

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: Probiotic supplements containing three strains of Lactobacillus acidophilus (2×109 CFU/g), Lactobacillus casei (2×109 CFU/g) and Bifidobacterium bifidum (2×109 CFU/g), daily, for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo capsule (Tak Gen Zist Pharmaceutical Company, Tehran, Iran), daily, for 12 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Naghavi cardiology Clinic
Full name of responsible person
Zatollah Asemi
Street address
Shahid Rajaee Avenue, Kashan
City
Kashan
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Isfehan
Postal code
8115187159
Phone
+98 31 5546 3378
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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
Street address
Ghotbe Ravandi Boulevard, Kashan
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+98 31 5546 3378
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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
Ph.D of Nutrition
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Position
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Other areas of specialty/work
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Person responsible for updating data

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Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
Ph.D of Nutrition
Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Web page address

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