

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Clinical trial of the effect of combined probiotic and vitamin D 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 vitamin D supplementation on metabolic profiles in type 2 diabetic patients with coronary heart disease (CHD).

Design

Study design: Randomized double-blind placebo-controlled trial. Patients will be assigned into two groups to receive melatonin supplements (n=30) or placebo (n=30).

Settings and conduct

Among diabetic patients and CHD referred to 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.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Individuals aged 45-85 years diagnosed with type 2 diabetes patients with coronary heart disease will be included in this study. Exclusion criteria: Exclusion criteria: Taking vitamin D, probiotic and/or synbiotic within the last 3 months, and patients with thyroid disorders.

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 vitamin D supplements (Zahravi, Tabriz, Iran), 50,000 IU vitamin D every 2 weeks, for 12 weeks orally. Control group: Probiotic and vitamin D placebo capsules (Barij essence, Kashan, Iran), probiotic placebo daily and vitamin D placebo every 2 weeks, 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

Acronym

IRCT registration information

IRCT registration number: **IRCT2017073033941N4**

Registration date: **2017-08-28, 1396/06/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-20, 1398/06/29**

Update count: **1**

Registration date

2017-08-28, 1396/06/06

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

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ostadmohammadi-vr@kaums.ac.ir

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

2017-08-29, 1396/06/07

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 vitamin D supplementation compared with the placebo on metabolic profiles in type 2 diabetic patients with coronary heart disease

Public title
Effect of combined probiotic and vitamin D supplementation in treatment of coronary heart disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Subjects aged 45-85 years Diagnosed with type 2 diabetes and CHD
Exclusion criteria:
Taking vitamin D, probiotic and/or synbiotic within the last 3 months Patients with thyroid disorders

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
Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
To decrease potential confounding effects, all participants will have stratified randomization according to BMI (<25 and ≥25 kg/m²) and age (<65 and ≥65 y). Then, participants in each block will be randomly allocated into two treatment groups to take either supplements or placebo. Randomization will be done by the use of computer software.

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

Isfahan

Postal code

8715988141

Approval date

2017-08-16, 1396/05/25

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1396.36

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

HDL

Timepoint

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

Method of measurement

Enzymatic kit

3

Description

Total cholesterol

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

Glutathione

Timepoint

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

Method of measurement

Spectrophotometry

7

Description

Malondialdehyde

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

Beck Depression Inventory

Timepoint

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

Method of measurement

Questionnaire

10

Description

Systolic blood pressure

Timepoint

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

Method of measurement

Manometer

11

Description

Diastolic blood pressure

Timepoint

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

Method of measurement

Manometer

12

Description

Beck Anxiety Inventory

Timepoint

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

Method of measurement

Questionnaire

13

Description

General Health Questionnaire

Timepoint

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

Method of measurement

Questionnaire

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 vitamin D supplements (Zahravi, Tabriz, Iran), 50,000 IU vitamin D every 2 weeks, for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Probiotic and vitamin D placebo capsules (Barij essence, Kashan, Iran), probiotic placebo daily and vitamin D placebo every 2 weeks, 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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Shahid Rajaee Avenue, Kashan

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Email

asemi_r@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

Street address

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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

Vice chancellor for research, 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

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Position

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Latest degree

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Other areas of specialty/work

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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

Person responsible for updating data**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Ghotbe Ravandi Boulevard, Kashan