Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Study of the effect of magnesium and zinc and probiotic co-supplementation on metabolic profiles in patients with coronary heart disease and type 2 diabetes mellitus

Protocol summary

Study aim

The aim of this study is to determine the effects of magnesium and zinc and probiotic co-supplementation on metabolic profiles; inflammatory factor and biomarkers of oxidative stress in patients with coronary heart disease and type 2 diabetes mellitus .

Design

randomized double blind , controlled with placebo and drug, parallel clinical trial on 60 patients.randomization will be done based on Stratified randomization using statistical software.

Settings and conduct

Patients with coronary artery disease and type 2 diabetes have been evaluated for inclusion criteria in the heart clinic of Kashan University of Medical Sciences affiliated to the University of Medical Sciences. Anthropometric indices; nutritional variables; metabolic profiles; inflammatory factors; and oxidative stress biomarkers are measured at the beginning of the study and after intervention.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Coronary heart disease patients diagnosed with angiography; Patients with diabetes according to American Diabetes Association criteria; age 40 to 95 years and Exclusion Criteria: thyroid disease; Acute myocardial infarction in the last 3 months; Cardiac surgery in the last 3 months; Significant kidney and liver failure; Unwillingness to cooperate; Antibiotic use during study.

Intervention groups

People at the beginning of the study will be placed in one of the two intervention groups (receiving magnesium and zinc supplements and probiotics) and the control group (placebo receiving the starch) once a day for 3 months.

Main outcome variables

The primary outcome is insulin resistance and the secondary consequences of changes in the metabolic profile; inflammatory factors and oxidative stress biomarkers.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130211012438N35**
Registration date: **2023-06-06, 1402/03/16**
Registration timing: **retrospective**

Last update: **2023-06-06, 1402/03/16**
Update count: **0**

Registration date

2023-06-06, 1402/03/16

Registrant information

Name
Mohsen Taghizadeh
Name of organization / entity
Kashan University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-05, 1397/10/15

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study of the effect of magnesium and zinc and probiotic co-supplementation on metabolic profiles in patients with coronary heart disease and type 2 diabetes mellitus

Public title
The effect of magnesium and zinc and probiotic co-supplementation in patients with coronary heart disease and type 2 diabetes mellitus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Coronary heart disease patients diagnosed with angiography; Patients with diabetes according to American Diabetes Association criteria; age 40 to 95 years; No smoking
Exclusion criteria:
Thyroid disease; Infection; Consumption of any type of supplement (vitamin, salts, etc.) in the last 3 months; Acute myocardial infarction in the last 3 months; Cardiac surgery in the last 3 months; Significant kidney failure; Significant liver failure; Unwillingness to cooperate; Antibiotic use during study
Age
From **40 years** old to **95 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The method of randomization is that the patients are placed on separate classes according to two criteria: BMI (BMI <25 BMI≥25) and age (<65 and 65≤), and then randomly in one of Two groups receiving magnesium and zinc supplements, and probiotics, and the placebo group (containing starch) are included. The study is done using the Stat Trek software.
Blinding (investigator's opinion)
Double blinded
Blinding description
Supplements and placebo after coding by the researcher are placed under supervision of clinical caregiver and then clinical caregiver provided them to the participants. Both clinical caregiver and participants are kept blind.
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
Kashan University of Medical Sciences, Pezeshk Ave., Qotb-e-Ravandi Blvd.
City
Kashan
Province
Isfehan
Postal code
8715988141
Approval date
2018-12-10, 1397/09/19
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1397.079

Health conditions studied

1

Description of health condition studied
coronary heart disease and type 2 diabetes mellitus
ICD-10 code
I25.9
ICD-10 code description
Chronic ischemic heart disease, unspecified

Primary outcomes

1

Description
Insulin resistance
Timepoint
Baseline and End-of-trial
Method of measurement
Calculate with HOMA formula

Secondary outcomes

1

Description
Fasting plasma glucose
Timepoint
Baseline and end of the trial
Method of measurement
Enzymatic

2

Description
Insulin
Timepoint
Baseline and end of the trial
Method of measurement
Elisa

3

Description
Insulin sensitivity
Timepoint
Baseline and end of the trial
Method of measurement
Calculate with QUICKI formula

4

Description
HbA1c
Timepoint
Baseline and end of the trial
Method of measurement
Laboratory clinical kit

5

Description
Nitric oxide (NO)
Timepoint
Baseline and end of the trial
Method of measurement
Spectrophotometry

6

Description
High sensitivity C-reactive protein (hs-CRP)
Timepoint
Baseline and end of the trial
Method of measurement
Elisa

7

Description
Total Antioxidant Capacity (TAC)
Timepoint
Baseline and end of the trial
Method of measurement
Spectrophotometry

8

Description
Total glutathione
Timepoint
Baseline and end of the trial
Method of measurement
Spectrophotometry

9

Description
Malondialdehyde (MDA)
Timepoint
Total glutathione
Method of measurement
Spectrophotometry

10

Description
Serum Total cholestrol
Timepoint
Baseline and end of the trial
Method of measurement
Laboratory clinical kit

11

Description
Serum LDL-C
Timepoint
Baseline and end of the trial
Method of measurement
Laboratory clinical kit

12

Description
HDL-C سرم
Timepoint
Baseline and end of the trial
Method of measurement
Laboratory clinical kit

13

Description
Serum Triglyceride
Timepoint
Baseline and end of the trial
Method of measurement
Laboratory clinical kit

Intervention groups

1

Description
Intervention group: A capsule containing 150 mg zinc sulfate and 250 mg magnesium oxide and a probiotic capsule (containing Lactobacillus acidophilus 109 × 1.8, Bifidobacterium bifidum 109 × 1.8, Bifidobacterium lactis 109 × 1.8 and Bifidobacterium Langum 109 x 1.8 CFU) Once a day for 3 months
Category
Treatment - Drugs

2

Description
Control group: 1000 mg Placebo capsule containing corn

starch once a day for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti hospital in kashan

Full name of responsible person

Dr Alireza Farrokhian

Street address

Shahid Beheshti Hospital, Pezeshk Ave., Qotb-e-Ravandi Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamid Reza Banafshe

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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

zahra Hamedifard

Position

Graduate student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
A portion of the data regarding demographics, anthropometric, and food variables, that are collected at the baseline of the study, and also the information on the main outcome will be shared.

When the data will become available and for how long
The start of the data access period will be one year after the publication of the results

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
In order to conduct meta analysis studies

From where data/document is obtainable
Mohsen Taghizadeh, Nutrition Department, School of Medicine, Kashan University of Medical Sciences, Qotbe-e-Ravandi Blvd., Kashan, Iran Postal Code: 88715973474 E-mail: sharifi-na@kaums.ac.ir Tel: 00983155540021 Fax: 00983155620608

What processes are involved for a request to access data/document
An applicant can send a request for a data file by e-mail. After reviewing the request, the data file will be sent to him/her after about three weeks would have passed from the date of the request

Comments