Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The effect of magnesium and zinc 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 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: patients with coronary disease on angiography ;patients with diabetes with American Diabetes Association; age 95-40 years and Exclusion Criteria: thyroid disease;No change in levels of LDL patients six weeks after the intervention; 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 groups receiving supplementation of magnesium and zinc and the placebo group (containing 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

The updating process was done before publishing the paper to correct the registration information.

Acronym

IRCT registration information

IRCT registration number: **IRCT20130211012438N31**
Registration date: **2019-05-11, 1398/02/21**
Registration timing: **retrospective**

Last update: **2020-05-27, 1399/03/07**
Update count: **1**

Registration date

2019-05-11, 1398/02/21

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

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

Public title

The effect of magnesium and zinc co-supplementation in patients with coronary heart disease and type 2 diabetes mellitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with coronary disease on angiography ;patients with diabetes with American Diabetes Association; age 40 to 95 years;No smoking

Exclusion criteria:

thyroid disease;No change in levels of LDL patients six weeks after the intervention;Infection; Consumption of any type of supplement (vitamin, mineral, etc.) by the patient 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

3

Groups that have been masked

- Participant
- Care provider
- Investigator

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 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

HOMA-Index

Timepoint

Baseline and End-of-trial

Method of measurement

Formula calculation

Secondary outcomes

1

Description

Fasting plasma glucose

Timepoint
Fasting plasma glucose
Method of measurement
Enzymatic

2

Description
Insulin
Timepoint
Baseline and End-of-tria
Method of measurement
Elisa

3

Description
QUICKI
Timepoint
Baseline and End-of-tria
Method of measurement
Formula calculation

4

Description
Beck Depression Inventory
Timepoint
Baseline and End-of-tria
Method of measurement
Questionnaire

5

Description
Nitric oxide (NO)
Timepoint
Baseline and End-of-tria
Method of measurement
Spectrophotometry

6

Description
High sensitivity C-reactive protein (hs-CRP)
Timepoint
Baseline and End-of-tria
Method of measurement
Elisa

7

Description
Total Antioxidant Capacity (TAC)
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

8

Description
Total glutathione
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

9

Description
Malondialdehyde(MDA)
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

10

Description
Serum Total cholestrol
Timepoint
Baseline and End-of-trial
Method of measurement
Laboratory clinical kit

11

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

12

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

13

Description
Serum Triglyceride
Timepoint
Baseline and End-of-trial
Method of measurement
Laboratory clinical kit

14

Description
Beck Anxiety Inventory
Timepoint
Baseline and End-of-trial
Method of measurement
Questionnaire

Intervention groups

1

Description

Intervention group: a capsule containing150 mg zinc sulfate and 250 mg magnesium oxide 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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Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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