

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 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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+98 36 1555 0021

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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
Isfahan
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-trial

Method of measurement

Elisa

3

Description

QUICKI

Timepoint

Baseline and End-of-trial

Method of measurement

Formula calculation

4

Description

Beck Depression Inventory

Timepoint

Baseline and End-of-trial

Method of measurement

Questionnaire

5

Description

Nitric oxide (NO)

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

6

Description

High sensitivity C-reactive protein (hs-CRP)

Timepoint

Baseline and End-of-trial

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 cholesterol

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 containing 150 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 Farrokhan

Street address

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

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Isfahan

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8115187159

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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

Street address

Kashan University of Medical Sciences, Pezeshk Ave., Qotb-e-Ravandi Blvd.

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Research@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

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

Nutrition

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Isfahan

Postal code

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