

# 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)

##### Phone

+98 36 1555 0021

##### Email address

taghizadeh\_m@kaums.ac.ir

##### 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

**City**

Kashan

**Province**

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8115187159

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**Email**

Farrokhan.ar@gmail.com

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

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**Email**

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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z.hamedifard.sb@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

mohsen taghizadeh

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

mohsen taghizadeh

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Kashan University of Medical Sciences, Kashan, Iran

**City**

Kashan

**Province**

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