

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of combined magnesium and vitamin E supplementation on metabolic profiles in patients of coronary artery bypass grafting (CABG) candidate

Protocol summary

Study aim

The effect of combined magnesium and vitamin E supplementation on metabolic profiles in patients of coronary artery bypass grafting (CABG) candidate

Design

This study is clinical trial and double blind. 60 patients with CABG candidate in Amiralmomenin hospital will enter.

Settings and conduct

This study is clinical trial and double blind. 60 patients with CABG candidate in Amiralmomenin hospital will enter. The patient is not aware of the treatment received. Participant and Analyzer are blind (double blind).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients candidate for CABG surgery; aged 40-85 years; no smoking; elective patients
Exclusion criteria: death; patients who are more than 8 hours after intubation; patients who are brought back to the operating room due to bleeding

Intervention groups

We use a supplement of magnesium 250 milligram (21st century, USA) daily for one week for 4 weeks of intervention. We used vitamin E supplements with a dose of 400 IU (Zahra company) daily for one week for 4 weeks after intervention. We used (Contains starch for magnesium and paraffin for vitamin E) with characteristics of the supplements in terms of color, shape and other design specifications, and the number of supplements for 4 weeks of intervention.

Main outcome variables

Effect of supplementation of magnesium and vitamin E on glucose, lipid profile and oxidative plasma biomarkers in patients undergoing CABG surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N71**

Registration date: **2018-03-13, 1396/12/22**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-13, 1396/12/22**

Update count: **0**

Registration date

2018-03-13, 1396/12/22

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-09, 1396/11/20

Expected recruitment end date

2020-02-09, 1398/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of combined magnesium and vitamin E supplementation on metabolic profiles in patients of coronary artery bypass grafting (CABG) candidate

Public title
The effect of combined magnesium and vitamin E supplementation on metabolic profiles in patients of coronary artery bypass grafting (CABG) candidate

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients candidate for CABG surgery Aged 40-85 years
No smoking Elective patients
Exclusion criteria:
death All patients who are more than 8 hours after intubation. All patients who are brought back to the operating room due to bleeding

Age
From **40 years** old to **85 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
simple randomization with use random numbers

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient is not aware of the treatment received.Participant and Analyzer are blind (double blind).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee Arak University Of Medical Sciences
Street address

Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak

City
Arak

Province
Markazi

Postal code
3814957558

Approval date
2018-01-21, 1396/11/01

Ethics committee reference number
IR.ARAK.MU.REC.1396.272

Health conditions studied

1

Description of health condition studied

Coronary artery bypass grafting

ICD-10 code

I25.700

ICD-10 code description

Atherosclerosis of coronary artery bypass graft(s), unspecified, with unstable angina pectoris

Primary outcomes

1

Description

blood suger

Timepoint

First and 1 month after intervention

Method of measurement

blood test

2

Description

Fat profile

Timepoint

First and 1 month after intervention

Method of measurement

blood test

3

Description

Oxidative stress biomarkers

Timepoint

First and 1 month after intervention

Method of measurement

blood test

4

Description

Anthropometric indicators

Timepoint

First and 1 month after intervention

Method of measurement

Strip meter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We use a supplement of magnesium 250 milligram (21st century, USA) daily for one week for 4 weeks of intervention.

Category

Treatment - Drugs

2

Description

Intervention group: We used vitamin E supplements with a dose of 400 IU (Zahra company)daily for one week for 4 weeks after intervention.

Category

Treatment - Drugs

3

Description

Control group: We used (Contains starch for magnesium and paraffin for vitamin E) with characteristics of the supplements in terms of color, shape and other design specifications, and the number of supplements for 4 weeks of intervention.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin hospital

Full name of responsible person

Dr Bijan Yazdi

Street address

Amiralmomenin hospital, Sardasht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Arjmandzadegan

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Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Latest degree

Specialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Yazdi

What processes are involved for a request to access data/document

They have to write letters to the professors and the university.

Comments