

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of selenium versus placebo on clinical symptoms after coronary artery bypass graft in patients with coronary artery stenosis: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of selenium versus placebo on clinical symptoms after coronary artery bypass graft in patients with coronary artery stenosis

Design

This is a double-blind randomized clinical trial, phase II, in which 60 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with coronary artery stenosis who will refer to Farshchian Heart Hospital during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 75 years Coronary artery stenosis An indication of coronary artery bypass graft
Exclusion criteria: Emergency patients A history of heart surgery Valvular disease

Intervention groups

Intervention group: Intravenous injection of selenium 100 mic gr single dose 10 min before detaching the pump
Control group: Intravenous injection of distilled water 2 ml single dose 10 min before detaching the pump us

Main outcome variables

Primary outcome: Assessing dysrhythmia Secondary outcome: Assessing inotrope usage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N223**

Registration date: **2018-06-14, 1397/03/24**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-14, 1397/03/24**

Update count: **0**

Registration date

2018-06-14, 1397/03/24

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-07-22, 1397/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of selenium versus placebo on clinical symptoms after coronary artery bypass graft in patients with coronary artery stenosis: a double-blind randomized clinical trial

Public title

Effect of selenium versus placebo on clinical symptoms after coronary artery bypass graft in patients with

coronary artery stenosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 75 years Coronary artery stenosis Indication of coronary artery bypass graft
Exclusion criteria:
Emergency patients A history of heart surgery Valvular disease

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of the patients to the intervention and control groups through the drawing of lots

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave
City
Hamadan
Province
Hamadan

Postal code
6517838695
Approval date
2015-04-11, 1394/01/22
Ethics committee reference number
UMSHA.REC.1394.31

Health conditions studied

1

Description of health condition studied
Coronary artery stenosis
ICD-10 code
I25.1
ICD-10 code description
Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description
Assessing dysrhythmia
Timepoint
Every 6 hours for 24 hours
Method of measurement
Using a monitor

Secondary outcomes

1

Description
Assessing inotrope usage
Timepoint
24 hours after surgery
Method of measurement
With checking patient's medical record

Intervention groups

1

Description
Intervention group: Intravenous injection of selenium 100 mic gr single dose 10 min before detaching the pump
Category
Treatment - Drugs

2

Description
Control group: Intravenous injection of distilled water 2 ml single dose 10 min before detaching the pump us
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Heart Hospital

Full name of responsible person

Sina Monazami Tabar

Street address

Farshchian Heart Hospital, Shahid Fahmideh Ave.

City

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6517838695

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+98 81 3838 1740

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sinamt@outlook.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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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

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Sina Monazami Tabar

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Afshin Farahanchi

Position

Anesthesiologist

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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