Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Investigating the effect of high dose of selenium on the Clinical Situation of patients undergoing coronary artery bypass surgery with a pump

Protocol summary

Study aim
Determining the effect of high doses of selenium in patients undergoing coronary artery bypass surgery

Design
A clinical trial with a control group, with parallel groups. No blinding. Phase 3 was randomized on 70 patients and balanced block was used for randomization.

Settings and conduct
It is an interventional and randomized controlled clinical trial study. The sample size is 70 people. They were referred to the heart surgery room of Shahid Beheshti Hospital, Qom, and after obtaining written consent, they were divided into two groups by randomization using the block randomization method: The first group: they receive a vial of 500 micrograms of selenium (manufactured by BIOSYN, Germany) before induction of anesthesia, a vial of 500 micrograms of selenium before transfer to the cardiopulmonary bypass pump, and finally a vial of 500 micrograms of selenium after Transfer the patient to the cardiopulmonary bypass pump. The second group: They receive normal saline at the same time as the first group, that is, before the induction of anesthesia, before transfer to the cardiopulmonary bypass pump and after transfer to the cardiopulmonary bypass pump.

Participants/Inclusion and exclusion criteria
Inclusion: age over 15 years; no history of allergy to selenium; candidate patients for on-pump CABG Exclusion : Sensitization to selenium, pregnancy, history of coagulation disorders Emergency surgery Off-pump CABG The presence of chronic diseases such as: patients with kidney dysfunction, patients with liver dysfunction, Patients with thyroid disorders

Intervention groups
The first group received high dose selenium and the second group received placebo (normal saline serum).

Main outcome variables
Clinical status

General information

Reason for update

Acronym
-

IRCT registration information
IRCT registration number: **IRCT20220614055165N1**
Registration date: **2023-07-18, 1402/04/27**
Registration timing: **prospective**

Last update: **2023-07-18, 1402/04/27**
Update count: **0**

Registration date
2023-07-18, 1402/04/27

Registrant information

Name
mohammad saeidi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 25 3612 2000

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dr.msaeidi@hotmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-23, 1402/06/01

Expected recruitment end date
2024-02-20, 1402/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of high dose of selenium on the Clinical Situation of patients undergoing coronary artery bypass surgery with a pump

Public title
Investigation of the effect of selenium on the treatment of patients undergoing coronary artery bypass surgery with a pump

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Candidate patients on-pomp with Coronary artery bypass graft surgery
Exclusion criteria:
Patients under Off- pomp Coronary artery bypass graft surgery

Age
From **15 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
This study will be performed by a random sampling method, block allocation. In such a way that In this study, 60 patients with corona will be randomly divided into two groups. The selection of groups will be based on the fact that individuals will be assigned to groups based on block randomization. Block size 4 is considered. So we have six blocks of four, ABAB, ABBA, AABB, BAAB BBAA, and BABA. The selection of each block will also be random and will be done using dice. For example, if the number 5 comes in the dice roll, the AABB block is considered Therefore, the first two patients are assigned to treatment A, and the two patients are then assigned to treatment B. The dice will be thrown ten times to complete the allocation of patients to treatment groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qom University of Medical Sciences
Street address
No. 83, Shahid Lotfi Niaser Ave, Safashehr Blvd
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3719964797

Approval date
2022-05-10, 1401/02/20

Ethics committee reference number
IR.MUQ.REC.1401.054

Health conditions studied

1

Description of health condition studied
Coronary Artery Bypass Graft Surgery

ICD-10 code
T82.218D

ICD-10 code description
Other mechanical complication of coronary artery bypass graft, subsequent encounter

Primary outcomes

1

Description
Clinical Situation

Timepoint
Before the start of the intervention, during the intervention

Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: One vial of 500 micrograms of selenium {BIOSYN manufacturer, made in Germany} before anesthesia induction, one vial of 500 micrograms of selenium before transfer to the cardiopulmonary bypass pump and one vial of 500 micrograms of selenium after transferring the patient to the cardiopulmonary bypass pump.

Category
Treatment - Drugs

2

Description
Control group: Control group: normal saline serum at the same time as the first group, i.e. before induction of anesthesia, before transfer to cardiopulmonary bypass pump and after transfer to cardiopulmonary bypass pump.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
Ghoum 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
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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
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable