

# 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)

##### Phone

+98 25 3612 2000

##### Email address

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-pump with Coronary artery bypass graft surgery

### Exclusion criteria:

Patients under Off- pump 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

#### City

Qom

#### Province

Ghous

#### Postal code

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**

Mohammad Saedi

**Street address**

Beheshti Hospital, Beheshti Blvd, Qom, Iran

**City**

QOM

**Province**

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**Postal code**

37719964797

**Phone**

+98 25 3612 2000

**Email**

dr.msaeidi@hotmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Ghous University of Medical Sciences

**Full name of responsible person**

Rahim Aali

**Street address**

No. 83, Shahid Lotfi Niaser Ave, Safashehr Blvd

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93456-37169

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**Email**

rahimalii@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ghous 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**

Ghous University of Medical Sciences

**Full name of responsible person**

Moahmmad Saeidi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Beheshti Hospital, Beheshti Blvd, Qom, Iran

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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Associate professor

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Specialist

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**Person responsible for updating data****Contact****Name of organization / entity**

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Ghoum

**Postal code**

3719964797

**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