

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

The effect of injectable selenium administration on serum lactate level in patients undergoing CABG

Protocol summary

Study aim

Investigation of changes in lactate levels and inflammatory factors in patients undergoing CABG surgery due to selenium injection

Design

The present clinical trial had a control group and an intervention in which the study population was randomly and individually based on random admission code. The project will be implemented in phase 0 clinical on 80 patients.

Settings and conduct

The clinical trial is being held at Masih Daneshvari Hospital in Tehran. Patients in the selenium group received 500 mg of selenium intravenously before surgery and at the same time at the end of surgery, while in the placebo group they received the same amount of normal saline. Patients are then anesthetized in the same way and placed on a heart pump. The variables are then measured during and after the operation in the ICU.

Participants/Inclusion and exclusion criteria

Entry requirements: - 18 < Age < 65 - EF = 40-55%
Conditions of non-entry: • Emergency surgery • Simultaneous valve and coronary surgery • Age over 75 years • History of kidney and liver disease (enzymes 2 times normal) • Drug sensitivity • Recent MI (in 7 days) • IABP before surgery • BMI < 12

Intervention groups

In total, 80 patients underwent CABG surgery in two control groups (40 patients) and intervention (40 patients) in this clinical trial.

Main outcome variables

Patient serum lactate levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150725023332N2**

Registration date: **2020-06-24, 1399/04/04**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-24, 1399/04/04**

Update count: **0**

Registration date

2020-06-24, 1399/04/04

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2283 1058

Email address

alirezajahangiri@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of injectable selenium administration on serum lactate level in patients undergoing CABG

Public title

The effect of selenium consumption in patients undergoing CABG surgery

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing CABG surgery 18 <Age <65

EF=40-55%

Exclusion criteria:

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this randomized trial, Sai was performed in a simple and individual manner with emphasis on patient admission code.

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 Shahid Beheshti University of Medical Sciences

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

City

Tehran

Province

Tehran

Postal code

1956944413

Approval date

2020-04-14, 1399/01/26

Ethics committee reference number

IR.SBMU.NRITLD.REC.1399.054

Health conditions studied

1

Description of health condition studied

Coronary Artery Bypass Grafting

ICD-10 code

I25.7

ICD-10 code description

Atherosclerosis of coronary artery bypass graft(s) and coronary artery of transplanted heart with angina pectoris

Primary outcomes

1

Description

Patient serum lactate levels

Timepoint

It is measured before and after the operation, two hours later, and then 6, 12, 18, and 24 hours after the operation.

Method of measurement

Biochemistry test (by turbulence-spectrophotometry method)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Selenium group (40 patients): 500 mg of selenium was given intravenously before surgery and at the same time at the end of surgery

Category

Treatment - Drugs

2

Description

Control group: Forty patients received 500 mg of normal saline intravenously before surgery and the same amount at the end of surgery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Msih Daneshvari hospital

Full name of responsible person

Alireza Jahangirifard

Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout

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Sponsors / Funding sources

1

Sponsor

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Position
Associate professor
Latest degree
Subspecialist

Other areas of specialty/work

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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

Not applicable

Data Dictionary

Not applicable