Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 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

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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
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Associate professor
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Person responsible for updating data

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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