Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of selenium added to the cardioplegic solution on cardiac protection in coronary artery bypass grafting surgeries And the comparison with the control group

Protocol summary

Study aim
Effect of selenium added to the cardioplegic solution on cardiac protection in coronary artery bypass grafting surgeries And the comparison with the control group

Design
In this double blind clinical trial, 66 patients were divided into control and intervention groups. The patients were allocated to the groups using random numbers table.

Settings and conduct
This study was performed on heart surgery centers in Shiraz. Patients undergoing coronary artery bypass graft surgery were enrolled and the investigator and patients did not know how to intervene..

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients undergoing coronary artery bypass Grafting surgery and referring to Shiraz state hospitals ؛ EF more than 30%. Exclusion Criteria: Pregnancy ؛ Combined or re-surgical procedures

Intervention groups
In the intervention group, 1000 micrograms of selenium (sodium selenite) in 20 cc volume was added to the cardioplegic solution and the control group, the same volume of normal saline was added to the cardioplegia solution.

Main outcome variables
Cardiac Troponin level; Arrhythmia; Post operative Drug and DC shock use; IntraAortic Ballon Pump usage

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180422039383N1**
Registration date: **2019-01-26, 1397/11/06**
Registration timing: **retrospective**
Last update: **2019-01-26, 1397/11/06**
Update count: **0**

Registration date
2019-01-26, 1397/11/06

Registrant information

Name
Masoud Abasi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 74 3226 1707

Email address
masooda1361@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-06-21, 1396/03/31

Expected recruitment end date
2017-09-11, 1396/06/20

Actual recruitment start date
2017-07-06, 1396/04/15

Actual recruitment end date
2017-11-11, 1396/08/20

Trial completion date
empty

Scientific title
Effect of selenium added to the cardioplegic solution on cardiac protection in coronary artery bypass grafting surgeries And the comparison with the control group

Public title
Study of the effect of selenium on myocardial protection

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Company satisfaction in research design EF more than 30% Age over 35 and under 80 Patients referred to the heart surgery room for CABG operation in government hospitals affiliated to Shiraz University of Medical Sciences.

Exclusion criteria:

Combination and redo surgery History of recent infarction (less than a week) pregnancy High troponin level (greater than 3µgl / lit /)

Age

From **35 years** old to **79 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **66**

Actual sample size reached: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly divided into control and intervention groups using random numbers table

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients did not have any information about the type of intervention and the intervention was performed during anesthesia and no information was given to the patient prior to anesthesia. And the information is completed by caregivers. After collecting information by a caregiver, this information is analyzed by a statistic expert.

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

the central building of Shiraz University of Medical Sciences, in front of the Felestine Street, Zand street, Shiraz.

City

shiraz

Province

Fars

Postal code

14336 - 71348

Approval date

2017-06-03, 1396/03/13

Ethics committee reference number

ir.sums.rec.1396.49

Health conditions studied

1

Description of health condition studied

Coronary Artery Bypass Graft Surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Cardiac Troponin marker: The most specific marker for heart damage.

Timepoint

Troponin: at pre-operative intervals, immediately after surgery, 6 and 24 hours after surgery.

Method of measurement

Troponin: Vidas Laboratory tool

2

Description

Arrhythmia :It is called a disturbance in the normal rhythm of the heart and a symptom of a disorder in the normal functioning of the heart.

Timepoint

From the de-clamping of aorta until the patient is delivered to the ICU.

Method of measurement

Monitoring of arrhythmias using cardiac monitoring and eye care.

3

Description

Drug use and DC shock: The use of medication and DC shock indicates the severity of the risk and the risk of arrhythmia, which can be studied by comparing it in two groups.

Timepoint

From the de-clamping of aorta until the patient is delivered to the ICU.

Method of measurement

Through observation and review of the doctor's order in the patient file documents.

4

Description
Intra Aortic Ballon Pump : In a condition, the contractile power of the heart is not sufficient is used and increases the contractile power of the heart.
Timepoint
After weaning of cardiopulmonary pump.
Method of measurement
Doctor's order.Patient File Documentation.

Secondary outcomes

1

Description
Blood Pressure
Timepoint
Before the operation, During the Cardiopulmonary Bypass, after cardiopulmonary bypass.
Method of measurement
Arterial Line

Intervention groups

1

Description
Intervention group: Adding 1000 microgram Selenium (Sodium selenite) to Cardioplegic Solution. The cardiopulmonary solution is then injected into the coronary arteries.
Category
Treatment - Drugs

2

Description
Control group: Adding 20 cc normal saline to cardioplegic solution. The cardiopulmonary solution is then injected into the coronary arteries.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi hospital
Full name of responsible person
Masood Abasi
Street address
Namazi Hospital,Namazi Square,Zand Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Sayed basir hashemi
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7134814336
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Email
president@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Masih Shafa
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
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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