

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 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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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 3µg/l / 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

Street address

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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

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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Position

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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