

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Assessment Effect of selenium injection on plasma level of TNF- α , IL-6, WBC, CRP, Glucose following CABG

Protocol summary

Summary

IHD constitutes 30% of patients who undergo surgery each year in the united states. One way to restore blood flow is CABG. Which leads to the release of inflammatory factors. This is a randomized clinical trial study , to evaluate selenium effect on inflammatory factors in patients undergoing cardiac surgery. The patients with normal levels of selenium are studied by randomly selecting a card in one of two groups receiving selenium and placebo. Before induction of anesthesia in selenium group 600 μ g selenium and in control group equivalent distilled water injected. In both groups induction done with similar values midazolam, sufentanyl and cis atra. In all patients, TNF- α , CRP, IL-6 were measured before induction, immediately after CPB, 24 and 48 hours after surgery. Finally the amount of inflammatory factors in two groups are compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015040813456N3**
Registration date: **2015-04-25, 1394/02/05**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-04-25, 1394/02/05

Registrant information

Name

Abbas Sedighinejad

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 911 132 5712

Email address

a_sedighinejad@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University Of Medical Sciences

Expected recruitment start date

2015-06-09, 1394/03/19

Expected recruitment end date

2015-12-10, 1394/09/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment Effect of selenium injection on plasma level of TNF- α , IL-6, WBC, CRP, Glucose following CABG

Public title

Effect of selenium injection on plasma level of TNF- α , IL-6, WBC, CRP, Glucose following CABG

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age 30-65 years old; ASA class 2-3 with 3 vessels occlusion and EF>40-45 % and normal preoperative level of selenium (for men: 29-107 μ g/l and for women: 27-150 μ g/l). Exclusion criteria: The pump more than 120 minutes; need to inotropic drugs; extubation over than 8-10 hours.

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 88

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Shahid Beheshti Freeway

City

Rasht

Postal code

4193833697

Approval date

2015-01-05, 1393/10/15

Ethics committee reference number

1930474201

Health conditions studied

1

Description of health condition studied

CABG with CPB

ICD-10 code

T80.8

ICD-10 code description

Other complications following infusion, transfusion and therapeutic injection

Primary outcomes

1

Description

Tumor necrosis factor alpha

Timepoint

Before induction, immediately after CPB, 24 and 48 hours after surgery

Method of measurement

Picogram per milliliter/Elisa metod

2

Description

IL-6

Timepoint

Before induction, immediately after CPB, 24 and 48 hours after surgery

Method of measurement

Picogram per milliliter/Elisa metod

3

Description

Glucose

Timepoint

Before induction, immediately after CPB, 24 and 48 hours after surgery

Method of measurement

mg/dl/autoanalasor RA-1000

4

Description

C-Reactive Protein

Timepoint

Before induction, immediately after CPB, 24 and 48 hours after surgery

Method of measurement

Reversed passive agglutination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention1: Selenium group 600 µg selenium injected, before induction of anesthesia

Category

Treatment - Drugs

2

Description

Intervention 2: control group(Placebo) equivalent distilled water injected, before induction of anesthesia

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmat Hospital

Full name of responsible person

Abbas Sedighinejad
Street address
Fifteenth Khordad Street
City
Rasht

Web page address
www.arc.gums.ac.ir

Person responsible for scientific inquiries

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research of Guilan University of Medical Sciences
Full name of responsible person
Abtin Heidarzadeh
Street address
Shahid Beheshti Freeway
City
Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Guilan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Abbas Sedighinejad
Position
Anesthesiologist
Other areas of specialty/work
Street address
Heshmat Hospital
City
Rasht
Postal code
4139638459
Phone
+98 13
Fax
+98 13 3334 5132
Email
aecguilan1392@gmail.com

Contact

Name of organization / entity
Guilan University of Medical Science
Full name of responsible person
Abbas Sedighinejad
Position
Anesthesiologist
Other areas of specialty/work
Street address
Dr.Heshmat Hospital
City
Rasht
Postal code
4193955599
Phone
+98 13 3331 0434
Fax
+98 13 3334 5132
Email
arcguilan1392@gmail.com
Web page address
www.arc.gums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Hedyeh Nemati
Position
Medical laboratory Sciences Technician/ Bachelor's Degree
Other areas of specialty/work
Street address
Poursina Hospital
City
Rasht
Postal code
4193713194
Phone
+98 13 3331 0434
Fax
+98 13 3334 5132
Email
nematihedieh@gmail.com
Web page address
www.arc.gums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan

empty
Informed Consent Form
empty
Clinical Study Report
empty

Analytic Code
empty
Data Dictionary
empty