

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Assessment Effect of selenium injection on plasma level of TNF- $\alpha$ , 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 $\mu$ 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- $\alpha$ , 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- $\alpha$ , IL-6, WBC, CRP, Glucose following CABG

##### Public title

Effect of selenium injection on plasma level of TNF- $\alpha$ , 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 $\mu$ g/l and for women: 27-150  $\mu$ 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*