

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial Comparing The Impact Of Selenium, Vitamine C And N-Acetylcystein On Prevention Of Acute Kidney Injury Following Off-Pump coronary artery bypass graft(CABG)

Protocol summary

Summary

Purpose: clinical trial comparing the impact of Selenium, Vitamine C And N-Acetylcystein (NAC) on prevention of acute kidney injury following off-pump CABG. This study is perspective, randomize and not blinded. 320 Patients had been studied by random number table in one of 4 groups (each group 80 patients) selenium, vitamin C, NAC and blank group. In first group 500 mg oral selenium (the trade name Selenase made by Biosyn Pharmacy company) was used in 14 hours before surgery, the dose was repeated 2 hours before surgery again. In vitamin C group, 1500 mg of Vitamin C (made by Exir, Tehran drug and Osve pharmacy companys) as 3 effervescent tablets, that 14 hours before surgery, the dose was repeated 2 hours before surgery again. NAC group received 600 ml/gr NAC (made by Exir pharmacy company) effervescent tablets 14 hours before surgery, the dose was repeated 2 hours before surgery again. Patients in the control group received only the routine care standard. In all of the patients, drug administration, as every 12 hours orally or by nasogastric gavage continued until 3 days after surgery, after surgery patients received a total of 8 doses of drugs. The total daily prescribed drugs to patients was 1,000 mcg of selenium, 3 grams in vitamin C group and NAC groups was equal to 1200 mg. Inclusion criteria: patient satisfaction; off-pump coronary artery bypass graft surgery method; there is no known history of renal including structural abnormalities; kidney failure or patients with a single kidney; non-emergency coronary artery bypass graft. Exclusion criteria: patients with chronic obstructive pulmonary disease; usage more than 2 units of blood during surgery; history of taking non-steroidal anti-inflammatory drugs; acute sepsis; patients with severe malnutrition; diabetes. Primary outcome: acute kidney injury in the form of increased serum creatinine or decreased urine output or both will be determined. Secondary outcome: stay in ICU

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015021621098N1**

Registration date: **2017-04-13, 1396/01/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-04-13, 1396/01/24

Registrant information

Name

Shahram Amini

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

aminish@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Mashhad University of Medical Sciences

Expected recruitment start date

2014-11-06, 1393/08/15

Expected recruitment end date

2015-03-06, 1393/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial Comparing The Impact Of Selenium, Vitamine C And N-Acetylcystein On Prevention Of Acute Kidney Injury Following Off-Pump coronary artery bypass graft(CABG)

Public title

Effects of selenium, vitamin C and N-acetylcysteine in the prevention of acute kidney injury after cardiac surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patient satisfaction; off-pump coronary artery bypass graft surgery method; there is no known history of renal including structural abnormalities; kidney failure or patients with a single kidney; non-emergency coronary artery bypass graft Exclusion criteria: patients with chronic obstructive pulmonary disease; usage more than 2 units of blood during surgery; history of taking non-steroidal anti-inflammatory drugs; acute sepsis; patients with severe malnutrition; diabetes.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **320**

Randomization (investigator's opinion)

Randomized

Randomization description**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 Mashhad University of Medical Sciences

Street address

Ghoreishi apartment, Daneshgah street, Mashhad

City

Mashhad

Postal code**Approval date**

2014-11-01, 1393/08/10

Ethics committee reference number

930080

Health conditions studied**1****Description of health condition studied**

Coronary Atrial Bypass Graft Pations

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes**1****Description**

Acute kidney injury

Timepoint

Before intervention and every one hour after intervention until the end of Hospitalization

Method of measurement

Measurement of serum creatinine and urine output

Secondary outcomes**1****Description**

Stay in ICU

Timepoint

Number of days of stay in ICU after surgery

Method of measurement

Day

Intervention groups**1****Description**

Intervention group 1 : 500 mg oral selenium (the trade name Selenase made by Biosyn Pharmacy company) was used in 14 hours before surgery, the dose was repeated 2 hours before surgery again

Category

Treatment - Drugs

2**Description**

Intervention group 2 : In vitamin C group, 1500 mg of Vitamin C (made by Exir, Tehran drug and Osve pharmacy companys) as 3 effervescent tablets, that 14 hours before surgery, the dose was repeated 2 hours before surgery again

Category

Treatment - Drugs

3**Description**

Intervention group 3 : NAC group received 600 ml/gr NAC (made by Exir pharmacy company) effervescent tablets 14 hours before surgery, the dose was repeated 2 hours before surgery again

Category

Treatment - Drugs

4**Description**

Control group: Received only routine care standard

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza hospital intensive care unit

Full name of responsible person

Dr Shahram Amini

Street address

Department of Anesthesia, Imam Reza Hospital, Ibne Sina street, Mashhad

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Mashhad University of Medical Science

Full name of responsible person

Hamid Eslami

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Ghoreishi apartment, Daneshgah street, Mashhad

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Mashhad

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, Mashhad University of Medical Science

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**

Mashhad University of Medical Sciences

Full name of responsible person

Shahram Amini

Position

Associate Professor

Other areas of specialty/work**Street address**

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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