

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparison of protective effects of N-acetyl cysteine and vitamin C on perioperative renal function in high-risk patients undergoing cardiac bypass surgery.

Protocol summary

Summary

Perioperative renal failure is one of the major complications following coronary artery surgeries, leading to increased morbidity and mortality rate in patients, necessitating renal replacement therapy and longer hospital and ICU stay. With regard to antioxidant effect of N-acetyl cysteine (NAC) and vitamin C in decreasing inflammatory factors, this study was designed to evaluate and compare the protective effects of these two agents on renal function of high-risk patients undergoing coronary artery surgeries. In this study, 84 patients above 70 years old, undergoing cardiac bypass surgery, who are considered as high-risk regarding postoperative renal failure are randomized into 3 groups; group 1 are received NAC, group 2 are received NAC plus vitamin C and group 3 are received normal saline(NS) 5% as placebo. The agents re administered during, 12 and 24 hours after the operation. Serum creatinine levels one day before and the 1st, 2nd and 3rd days after operation are recorded and compared. Note that subjects experienced heart and kidney transplant are excluded from the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014072815102N4**
Registration date: **2014-08-22, 1393/05/31**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-22, 1393/05/31

Registrant information

Name

Soheil Ashkani-Esfahani

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research affairs, Shiraz University of Medical Sciences

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2014-05-22, 1393/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of protective effects of N-acetyl cysteine and vitamin C on perioperative renal function in high-risk patients undergoing cardiac bypass surgery.

Public title

The effect of N-acetyl cysteine and vitamin C on kidney in patients undergoing open heart surgery.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age above 70 years old; Renal failure;

Serum Cr level above 1.4 mg/dl; Heart ejection fraction of below 35%; Concomitant valve surgery with bypass surgery; History of previous coronary artery surgeries; Diabetes under treatment with oral agents or insulin. Exclusion criteria: The emergency cardiac bypass surgery; History of heart transplantation; Acute renal failure; Serum Cr level higher than 4.5 mg/dl; History of renal transplantation; N-acetyl cysteine consumption in the last 5 days prior to the operation.

Age

From **70 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Eighty four patients with coronary artery disease, who are selected for bypass surgery and considered high-risk regarding renal complications, are randomly divided into 3 groups. All groups are equal regarding their age averages. The intervention group1 is given N-acetyl cysteine, intervention group 2 is given N-acetyl cysteine plus vitamin C and control one is received placebo. Since the study was a double blind one, patients and surgical group do not know which one is medication and which one is placebo.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shiraz University of Medical Sciences

Street address

School of Medical Sciences, Zand St.

City

Shiraz

Postal code**Approval date**

2014-04-15, 1393/01/26

Ethics committee reference number

ct-p-9356-5306

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

Renal failure

ICD-10 code

N17

ICD-10 code description

Acute renal failure

2**Description of health condition studied**

coronary vessel disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerosis heart disease

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

the effect of N-acetyl cysteine on kidney

Timepoint

the 1st, 2nd and 3rd day after surgery

Method of measurement

Serum creatinine level

2**Description**

The effect of N-acetyl cysteine and vitamin C on kidney

Timepoint

the 1st, 2nd and 3rd day after surgery

Method of measurement

Serum creatinine levels

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

blood pressure

Timepoint

before surgery

Method of measurement

the peripheral blood pressure was measured with sphygmomanometer

2**Description**

number of grafts

Timepoint

after surgery

Method of measurement

review of operation note

Intervention groups

1

Description

Intervention1: Acetyl cysteine (EXI-NACE, EXIR pharmaceuticals, Borujerd, Iran), 2gr/lit injectable ampule, 3ml, 4doses within 24 hours after surgery.

Category

Treatment - Drugs

2

Description

Intervention 2: placebo, 2gr/lit injectable ampule, 3ml, 4doses within 24 hours after surgery.

Category

Treatment - Drugs

3

Description

intervention3: vitamin C (OSVE-VITAMIN C, Osve pharmaceuticals, Tehran, Iran), 500mg/5ml injectable ampule, 30 ml, 4 doses within 24 hours after surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

hospitals affiliated to Shiraz University of Medical Sciences

Full name of responsible person

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research affairs, Shiraz University of Medical Sciences

Full name of responsible person

Seyed Basir Hashemi

Street address

Shiraz University of Medical Sciences, Zand St.

City

Shiraz

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 affairs, Shiraz 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

Department of Anesthesiology and Student Research Committee

Full name of responsible person

Saeed Reza Soltani

Position

Resident of Anesthesiology

Other areas of specialty/work

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Name of organization / entity

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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