Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigation of the effect of N-acetyl cysteine on renal function after coronary artery bypass graft surgery

Protocol summary

Study aim

The effect of acetylcysteine on renal injury prevention after open heart surgery

Design

In this study, 60 patients with blind double-sided blind clinical trial were randomly divided into two groups of intervention and control.

Settings and conduct

In this study, 60 patients who are candidates for open heart surgery in Golestan Hospital of Ahvaz will be selected as available and will be divided into two groups of intervention and control in a simple random manner. They will receive mg/kg of N-acetyl cysteine. In the control group, after induction of anesthesia and intubation, 150 mg / kg normal saline will be given intravenously. In order to conduct a two-way blind study of patients and researchers who inject the drug and take a blood sample from They don't know which medicine or which drug.

Participants/Inclusion and exclusion criteria

Criteria for admission: Open heart surgery; age 30 to 70 years; normal kidney and liver function; no diabetes, hypertension, thyroid dysfunction and cardiac arrhythmia; no addiction, Glomerular filtration less than 60.

Intervention groups

In the intervention group, after induction of anesthesia and intubation, 150 mg / kg N-acetylcysteine will be administered intravenously. In the control group, after induction of anesthesia and intubation, 150 mg / kg normal saline will be administered intravenously.

Main outcome variables

Patients who entered the study would be screened for serum creatinine levels, nitrogen in the blood, glomerular filtration in a blood test, and urinary albumin after open heart surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190506043492N3**
Registration date: **2020-06-07, 1399/03/18**
Registration timing: **retrospective**

Last update: **2020-06-07, 1399/03/18**
Update count: **0**

Registration date

2020-06-07, 1399/03/18

Registrant information

Name

Milad Arabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3001

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arabi.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-22, 1397/02/02

Expected recruitment end date

2020-02-09, 1398/11/20

Actual recruitment start date

2018-04-25, 1397/02/05

Actual recruitment end date

2020-02-14, 1398/11/25

Trial completion date

2020-03-18, 1398/12/28

Scientific title

Investigation of the effect of N-acetyl cysteine on renal function after coronary artery bypass graft surgery

Public title
The effect of N-acetyl cysteine on renal function after open heart surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Candidates for open heart surgery. Be 30 to 70 years old. Have normal kidney and liver functionDo not have thyroid disease, hypertension, diabetes and arrhythmia. Don't be addicted to drugs. Glomerular filtration should be less than 60.
Exclusion criteria:
The patient is not satisfied to participate in the study. If the patient is taking renal effective drugs such as steroids and anti-inflammatory. If you are allergic to N-acetyl cysteine.
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients were randomly selected and divided into two groups of interventions (recipient of N-acetyl cysteine) and control (normal recipient of saline) through a table of random numbers assigned to even numbers for the intervention group and individual numbers for the control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, patients were unaware that they were in the receiving group of N-acetyl cysteine or normal saline, The person injecting the drug did not know if the syringe contained N-acetyl cysteine or normal saline, Because the drug was taken by another anesthesiologist and labeled 1 and 2, and Finally, the person who took the blood sample from the patients for renal tests did not know the type of intervention and the type of medicine that had been injected for the patients.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of ahvaz jundishapur University of Medical Sciences
Street address
Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan BLvd., Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
61357157941
Approval date
2019-08-19, 1398/05/28
Ethics committee reference number
IR.AJUMS.REC.1398.392

Health conditions studied

1

Description of health condition studied
kidney disease
ICD-10 code
I13
ICD-10 code description
Hypertensive heart and chronic kidney disease

Primary outcomes

1

Description
The effect of N-acetyl cysteine on renal factors after open heart surgery
Timepoint
Before anesthesia, 1,3,12, 24 and 48 hours later
Method of measurement
Serum level of creatinine in blood tests

2

Description
The effect of N-acetyl cysteine on renal factors after open heart surgery
Timepoint
Before anesthesia, 1,3,12, 24 and 48 hours later
Method of measurement
Serum level of BUN in blood tests

3

Description

The effect of N-acetyl cysteine on renal factors after open heart surgery

Timepoint

Before anesthesia, 1,3,12, 24 and 48 hours later

Method of measurement

Serum level of GFR in blood tests

4

Description

The effect of N-acetyl cysteine on renal factors after open heart surgery

Timepoint

Before anesthesia, 1,3,12, 24 and 48 hours later

Method of measurement

Urinary albumin levels

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After induction of anesthesia and intubation, they will receive 150 mg / kg n-acetylcysteine intravenously (Oxy-Nak, Elixir Pharmacy, Boroujerd, Iran).

Category

Prevention

2

Description

Control group: After induction of anesthesia and intubation, intravenous administration of 150 mg / kg normal saline will be given.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Zahra Shaker

Street address

Golestan Hospital, Golestan Boulevard

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Khouzestan

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6135715794

Phone

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Email

Shaker.z@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Zahra shaker

Position

Associate Professor

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact
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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable