Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

The effect of intravenous administration of N-acetylcysteine during cardiopulmonary bypass on hepatic and renal function and cardiac enzymes in patients undergoing coronary artery bypass surgery

Protocol summary

Study aim

Determination of the effect of intravenous N-acetylcysteine administration during cardiopulmonary bypass on hepatic and renal function and cardiac enzyme levels in patients undergoing coronary artery bypass graft (CABG) surgery

Design

A phase III randomized, single-blind, controlled clinical trial with parallel groups conducted on 66 patients. Randomization will be performed using the RAND function in Microsoft Excel.

Settings and conduct

This study will be conducted on patients candidate for coronary artery bypass graft (CABG) surgery at Shahid Rajaei Cardiovascular Hospital. Patients will be block-randomized into two groups: the N-acetylcysteine (NAC) group and the control group.Patients in the NAC group will receive 100 mg/kg of N-acetylcysteine added to the priming solution and an additional 100 mg/kg administered before removal of the cross-clamp.

Participants/Inclusion and exclusion criteria

All adult patients (over 18 years of age) undergoing first-time elective coronary artery bypass graft (CABG) surgery. Patients with a left ventricular ejection fraction (LVEF) of 30% or higher.

Intervention groups

For this study, patients undergoing cardiopulmonary bypass (CPB) and coronary artery bypass graft (CABG) surgery will be randomly assigned, using block randomization, into two groups: the N-acetylcysteine (NAC) group and the control group.Patients in the N-acetylcysteine group will receive 100 mg/kg of NAC added to the priming solution and an additional 100 mg/kg administered before removal of the cross-clamp.In the control group.

Main outcome variables

N-acetylcysteineCardiac EnzymesDuration of Cross-Clamp Use of Blood ProductsArterial, Blood Gases (ABG),Inotrope Number of Shocks,BUN–Creatinine Level Duration of Mechanical Ventilation,Length of Hospital Stay Liver Function Tests ,(LFT)Reoperation Use of Intra-Aortic Balloon Pump (IABP) Arrhythmia, Mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250901067077N1**
Registration date: **2025-10-24, 1404/08/02**
Registration timing: **registered_while_recruiting**

Last update: **2025-10-24, 1404/08/02**
Update count: **0**

Registration date

2025-10-24, 1404/08/02

Registrant information

Name

Ali Kheirabadi

Name of organization / entity

Shaheed Rajaie Cardiovascular Medical and Research Center

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-18, 1404/07/26

Expected recruitment end date
2025-12-17, 1404/09/26
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of intravenous administration of N-acetylcysteine during cardiopulmonary bypass on hepatic and renal function and cardiac enzymes in patients undergoing coronary artery bypass surgery

Public title
Administration of liver and kidney protective agent
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All adult patients (over 18 years of age) undergoing first-time elective coronary artery bypass graft (CABG) surgery. Patients with a left ventricular ejection fraction (LVEF) of 30% or higher.
Exclusion criteria:
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider

Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
The study is a single-blind clinical trial in which block randomization will be used for the allocation of subjects, and the patients will be unaware of the type of intervention. This research will be conducted on patients undergoing coronary artery bypass graft (CABG) surgery with cardiopulmonary bypass (CPB) at Shahid Rajaei Cardiovascular, Medical, Research, and Training Center in the year 2025 (1404 Iranian calendar). Data will be collected using data collection forms (attached) containing clinical information extracted from patients' medical records, including name, surname, age, sex, height, weight, diagnosis, type of surgery, attending physician and surgeon, as well as clinical outcome results. To identify eligible participants, the researcher will obtain a list of medical records of patients scheduled for Tetralogy of Fallot surgery from the relevant department heads. Then, based on a review of these medical records, patients who meet the inclusion criteria will be continuously recruited as study samples.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is single-blind, in which the clinical caregiver is unaware of the intervention procedure.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Cardiovascular Research Center, Rajaie Cardiovascular Institute
Street address
Valiasr Avenue (A.S.) – Next to Mellat Park – at the corner of Niayesh – Shahid Rajaei Cardiovascular, Medical, Research, and Training Institute
City
Tehran
Province
Tehran
Postal code
1995614331
Approval date
2025-07-06, 1404/04/15
Ethics committee reference number
IR.RHC.REC.1404.079

Health conditions studied

1

Description of health condition studied
Patients with coronary artery involvement
ICD-10 code
I25.1
ICD-10 code description

Primary outcomes

1

Description
Postoperative cardiac enzyme levels are lower in the intervention group.
Timepoint
Evaluation of patients' liver function tests (LFTs) before and after surgery – assessment of reoperation due to bleeding – evaluation of inotropes used during surgery and within 24 hours after ICU admission.
Method of measurement
The measurement of cardiac enzymes is performed using the corresponding laboratory test kits.

Secondary outcomes

1

Description
Reduction in length of stay in the intensive care unit (ICU)
Timepoint
The time points for measuring the length of hospital stay as a secondary outcome are 48 to 72 hours postoperatively.
Method of measurement
The method of measurement is based on the corresponding checklist

Intervention groups

1

Description
Intervention group:Intervention group: Patients will be randomly divided into two groups receiving N-acetylcysteine and a control group. Patients in the receiving group will receive 100mg/kg N-acetylcysteine ampoule in prime solution and 100mg/kg before cross-clamp removal.
Category
Treatment - Drugs

2

Description
Control group:Control group: Patients in the control group will not receive any intervention. ABG will also be monitored every hour during the pump and every 6 hours after the operation. All stages of anesthesia, operation, and cooling and warming are performed identically in both groups. The location of this study is the operating room and intensive care unit of Shahid Rajaee Heart Hospital.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaei Cardiovascular, Medical, Research, and Training Institute
Full name of responsible person
Ali Kheyrabadi
Street address
Valiasr Avenue (A.S.) , Next to Mellat Park ,at the corner of Niayesh ,Shahid Rajaei Cardiovascular, Medical, Research, and Training Institute
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Pasture Institute of Iran
Full name of responsible person
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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
Pasture Institute of Iran
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
Shahid Rajaei Cardiovascular, Medical, Research, and Training Institute
Full name of responsible person
Ali Kheyabadi
Position
Nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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