Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effect of N-Acetylcysteine and Vitamin C Supplementation of Cardioplegic Solution on Changes in Postoperative Serum Cardiac Troponin Levels Following On-Pump Coronary Artery Bypass Grafting

Protocol summary

Study aim

To determine and compare the effects of adding N-acetylcysteine and vitamin C to cardioplegic solution on postoperative serum cardiac troponin levels in patients undergoing on-pump coronary artery bypass grafting.

Design

Randomized, double-blind, parallel-group clinical trial using block randomization, conducted among 70 patients scheduled for on-pump coronary artery bypass grafting (CABG).

Settings and conduct

Patients scheduled for on-pump coronary artery bypass grafting (CABG) at Amir al-Momenin Hospital in Arak will be screened based on predefined eligibility criteria and allocated into two intervention groups (A and B) using web-based block randomization. In this double-blind trial, the patients, perfusionists, and cardiac surgeon will remain blinded to the assigned treatments.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients aged 30–75 years who are candidates for on-pump coronary artery bypass grafting (CABG), have no history of previous cerebrovascular events, and present with written informed consent. Exclusion Criteria: Concomitant cardiac valve repair or replacement during CABG, prolongation of operative duration beyond 6 hours, and requirement for reinstitution of cardiopulmonary bypass during surgery.

Intervention groups

Patients in Group A and Group B will receive 50 mg/kg of Vitamin C (Alborz Pharmaceutical) and N-acetylcysteine (Exir Pharmaceutical), respectively, added to the cardioplegic solution during the procedure.

Main outcome variables

For each patient in Groups A and B, serum cardiac troponin (cTn) levels will be measured using quantitative troponin assay kits before surgery and at 24 and 48 hours after open-heart surgery. The results will be recorded and analyzed. In addition, the percentage changes in serum cardiac troponin levels at the specified time points will be compared between the intervention groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260731070458N1**
Registration date: **2026-10-01, 1405/07/09**
Registration timing: **prospective**

Last update: **2026-10-01, 1405/07/09**
Update count: **0**

Registration date

2026-10-01, 1405/07/09

Registrant information

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-23, 1405/08/01

Expected recruitment end date
2026-12-22, 1405/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effect of N-Acetylcysteine and Vitamin C Supplementation of Cardioplegic Solution on Changes in Postoperative Serum Cardiac Troponin Levels Following On-Pump Coronary Artery Bypass Grafting

Public title
Evaluation of the effects of the combination of cardioplegic solution and N-acetylcysteine compared with the combination of cardioplegic solution and vitamin C on the serum level of cardiac troponin after on-pump coronary artery bypass surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients scheduled for coronary artery bypass grafting (CABG) who presented to Amir al-Momenin Medical Center in Arak and provided written informed consent to undergo CABG surgery. Patients undergoing open-heart surgery exclusively for CABG, with no indication for concomitant cardiac valve repair or replacement, or cardiac wall reconstruction procedures. Patients who had completed routine preoperative laboratory evaluations and were considered eligible for cardiac surgery, with no contraindications or clinically significant conditions precluding surgery. No history of cerebrovascular accident (CVA). Expected operative duration of 5–6 hours. CABG performed using cardiopulmonary bypass (on-pump CABG). Patients aged 30–75 years.
Exclusion criteria:
Performance of concomitant cardiac valve repair or replacement during coronary artery bypass grafting (CABG). Extension of the CABG operative time beyond 6 hours. Requirement for reinstitution of cardiopulmonary bypass during CABG due to the patient’s inability to tolerate separation from cardiopulmonary bypass.
Age
From **30 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization Method: Block randomization Unit of Randomization: Individual participant Description of Randomization Procedure: Given the planned sample size, permuted blocks of four participants will be used. Group 1 will receive vitamin C added to the cardioplegic solution (Group A), whereas Group 2 will receive N-acetylcysteine added to the cardioplegic solution (Group B). For each block of four participants, the six possible allocation sequences are: AABB, BBAA, ABAB, BABA, ABBA, BAAB. One sequence will be selected at random for each block. Before participant enrollment begins, a random allocation list corresponding to the total required sample size will be generated based on these randomly selected block sequences. Randomization Tool and Allocation Concealment: A web-based randomization program will be used to generate the allocation sequence. The program will create randomly permuted treatment assignments for both study groups within each block. Because the order of treatment allocations varies randomly across blocks, allocation concealment will be maintained and the investigator’s ability to predict the treatment assignment of subsequent participants during the study will be minimized. Web-based tool used for random permuted-block allocation: https://www.sealedenvelope.com/simple-randomiser/v1/lists
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the two investigational agents will be prepared by an anesthesiologist in identical syringes of the same color, size, and appearance, according to each patient’s clinical condition. The syringes will be labeled using coded identifiers and provided to the cardiopulmonary bypass (CPB) team for administration. Patients receiving vitamin C added to the cardioplegic solution will be assigned to Group A, while those receiving N-acetylcysteine added to the cardioplegic solution will be assigned to Group B. The patients and the perfusionists responsible for operating the cardiopulmonary bypass machine will remain unaware of the study-group assignments and the contents of the syringes. Only the anesthesiologist, through the syringe coding system, will be aware of the allocated intervention. Furthermore, the cardiac surgeon will be blinded to the treatment allocation and the identity of the administered investigational agent throughout the surgical procedure. Therefore, because the patients, perfusionists, and cardiac surgeon are blinded to the intervention, the study will be conducted as a double-blind clinical trial.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Arak University of Medical Sciences

Street address
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Approval date
2026-04-12, 1405/01/23

Ethics committee reference number
IR.ARAKMU.REC.1405.029

Health conditions studied

1

Description of health condition studied
On-pump coronary artery bypass grafting

ICD-10 code
I21

ICD-10 code description
ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description
Postoperative serum cardiac troponin levels following on-pump coronary artery bypass grafting

Timepoint
Measurement of serum cardiac troponin levels before surgery (prior to initiation of the intervention) and at 24 and 48 hours after completion of surgery.

Method of measurement
Laboratory kits for measuring serum cardiac troponin levels

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: Participants in this group, designated as Group A, will receive vitamin C at a dose of 50 mg/kg, manufactured by Alborz Pharmaceutical Company, during the initial stages of on-pump coronary artery bypass grafting (CABG). Vitamin C will be administered in combination with, and concurrently with, cold cardioplegic solution.The required dose of cardioplegic solution will be administered after aortic cross-clamping and during the induction of cardiac arrest, as determined by the cardiac surgeon and in accordance with the manufacturer’s recommendations and guidelines provided by Shahid Ghazi Pharmaceutical Company, the manufacturer of the cardioplegic solution.

Category
Treatment - Drugs

2

Description
Second intervention group: Participants in this group, designated as Group B, will receive N-acetylcysteine (NAC) at a dose of 50 mg/kg, manufactured by Exir Pharmaceutical Company, during the initial stages of on-pump coronary artery bypass grafting (CABG). NAC will be administered in combination with, and concurrently with, cold cardioplegic solution.The required dose of cardioplegic solution will be administered after aortic cross-clamp placement and during induction of cardiac arrest, as determined by the cardiac surgeon and in accordance with the recommendations and guidelines of Shahid Ghazi Pharmaceutical Company, the manufacturer of the cardioplegic solution.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
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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
Arak 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

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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

Not applicable

Data Dictionary

Not applicable