Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of N-acetyl cysteine in Prime solution on reducing myocardial stress in coronary artery bypass surgery

Protocol summary

Study aim
Determining the effect of Nacetylcysteine on reducing Stress to the myocardium in coronary artery bypass surgery

Design
This study is a double-blind clinical trial. Patients are divided into intervention and control groups by a simple random method (by software). The sample size is 20 cases in each group. In the intervention group, N-acetylcysteine (25mg/kg) was added to the prime solution, and in the control group, an equivalent volume of placebo (normal saline) was prescribed. SPSS software is used for data analysis.

Settings and conduct
Sampling is done from patients undergoing coronary artery bypass surgery in Shahid Chamran Hospital, Isfahan. Clinical staff, patients and data analyst in the study do not know the type of intervention for patients. Patients randomly participated in one of two groups, Nac and placebo The dose of the intervention group is added to the prime solution, N-acetylcysteine (25mg/kg) and in the control group, an equivalent volume of placebo (normal saline) is administered.

Participants/Inclusion and exclusion criteria
Main conditions for entering the study: age 40-70 years, coronary artery transplant candidate, EF ≥ 50% Major exclusion conditions: EF less than 50, asthma, kidney failure, sensitivity to NAC

Intervention groups
Patients are randomly divided into 2 intervention-control groups. In the intervention group, N-acetylcysteine (25mg/kg) is added to the prime solution, and in the control group, an equivalent volume of placebo (normal saline) is prescribed.

Main outcome variables
Investigation of damage to the myocardium by measuring indicators: troponin I before operation, immediately after operation and 8 hours after operation / CRP before operation, immediately after operation and 24 hours after operation / need for shock and pacemaker

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230218057443N1**
Registration date: **2023-06-13, 1402/03/23**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-13, 1402/03/23**
Update count: **0**

Registration date
2023-06-13, 1402/03/23

Registrant information

Name
Bahareh Baharifar

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3650 3663

Email address
b.baharifar70@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-10, 1402/03/20

Expected recruitment end date
2023-08-21, 1402/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of N-acetyl cysteine in Prime solution on reducing myocardial stress in coronary artery bypass surgery

Public title
The effect of N-acetylcysteine on myocardial stress in coronary artery bypass surgery

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients candidates for CABG surgery informed consent age (40-70) years ejection fraction EF ≥ 50%) non-emergency patients, patients with stable hemodynamics patients who did not use ECMO and balloon pump before surgery

Exclusion criteria:

Age
From **40 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: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization of patients between two groups is done by Selde random method and using random assignment software (RAS). In this software, the total number of sample size (40 people) and the number of groups (two groups) are entered into the software. The output of the software includes a list that randomly distributes the numbers 1 to 40 in two groups. Patients are entered into one of the two groups according to the time of visiting the hospital and according to the mentioned list, so that the sample size reaches the required number in each group.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the participants, clinical caregivers (laboratory, operating room personnel, nurses), those who evaluate the outcome and those who analyze the data are unaware of the type of drug received and these people do not know which the participant is in. The group (intervention/control) is located.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Isfahan, Salman Farsi Street, after Shahristan Bridge, Martyr Dr. Chamran Heart Hospital

City
Isfahan

Province
Isfehan

Postal code
8997-881583

Approval date
2023-05-31, 1402/03/10

Ethics committee reference number
IR.MUI.MED.REC.1402.103

Health conditions studied

1

Description of health condition studied
کاهش خونرسانی سرخرگ‌های قلب

ICD-10 code
I25.1

ICD-10 code description
Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description
Troponin

Timepoint
Before surgery, immediately and eight hours after surgery

Method of measurement
Venous blood sample

2

Description
CRP

Timepoint
Before surgery, immediately and 24 hours after surgery

Method of measurement
Venous blood sample

Secondary outcomes

1

Description
Duration of stay in ICU
Timepoint
Time of discharge from ICU
Method of measurement
patient file

2

Description
Need for defibrillator shock during surgery
Timepoint
during surgery
Method of measurement
view

3

Description
The need for a pacemaker during surgery
Timepoint
during surgery
Method of measurement
view

Intervention groups

1

Description
Intervention group: N-acetyl cysteine ampoule at the rate of 20 mg per kilogram of body weight in Prime solution in the cardiopulmonary bypass circuit.
Category
Treatment - Drugs

2

Description
Control group: equivalent volume of intervention drug from normal saline as placebo in Prime solution in cardiopulmonary bypass circuit
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Chamran Heart Hospital, Isfahan
Full name of responsible person
Dr. Mehran Shahzamani
Street address
Salman Farsi Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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Mushtaq AAve, Chamran Hospital
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Mehran Shahzamani
Position
Assistant Professor
Latest degree
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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
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available