# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

01 Aug 2026

## Effects of N-acetyl cysteine on the improvement of cardiopulmonary and renal functions after cardiopulmonary bypass in patients with coronary artery bypass graft

## Protocol summary

**Study aim**
Effects of N-acetylcysteine on the improvement of cardiopulmonary and renal functions after cardiopulmonary bypass in patients with coronary artery bypass graft

**Design**
The clinical trial has a community-based, practice-oriented control group, with parallel groups, randomized

**Settings and conduct**
The effect of n-acetylcysteine during open heart surgery was performed in the heart surgery department at three different times.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria were patients with age 25-75 years undergoing CPB for CABG. Exclusion criteria were patients for emergency CABG, redo CABG, and the intubation time after surgery for more than >10 hours and severe hemorrhage during CABG.

**Intervention groups**
In this study, an intervention group and a control group participated.In intervention group after induction, a central venous line was inserted and first blood sample (pre-CPB time) was obtained. After this stage, the intervention group received 100 mg/kg NAC into one liter normal saline and the control group received one liter normal saline one hour before initiating CPB.

**Main outcome variables**
Pao2/Fio2- A-a gradient - Shunt- Interleukin-6 - CRP - CKMB - Troponine- Serum Lactate- Creatinine - Ejection fraction

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20150825023760N8**
Registration date: **2019-03-12, 1397/12/21**
Registration timing: **retrospective**

Last update: **2019-03-12, 1397/12/21**
Update count: **0**

**Registration date**
2019-03-12, 1397/12/21

**Registrant information**

**Name**
Mohammad Reza Jamshidi

**Name of organization / entity**
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2013-12-10, 1392/09/19

**Expected recruitment end date**
2014-12-10, 1393/09/19

**Actual recruitment start date**
2015-05-27, 1394/03/06

**Actual recruitment end date**
2017-11-16, 1396/08/25

**Trial completion date**
2017-11-26, 1396/09/05

**Scientific title**
Effects of N-acetyl cysteine on the improvement of cardiopulmonary and renal functions after cardiopulmonary bypass in patients with coronary artery

bypass graft

**Public title**
Effects of N-acetyl cysteine on the improvement of cardiopulmonary and renal functions
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Inclusion criteria were patients with age 25-75 years undergoing cardio pulmonary bypass (CPB) for coronary artery bypass graft(CABG).
**Exclusion criteria:**
Exclusion criteria were patients for emergency coronary artery bypass graft(CABG) Redo CABG The intubation time after surgery for more than >10 hours Severe hemorrhage during coronary artery bypass graft (CABG)
**Age**
From **25 years** old to **75 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **50**
Actual sample size reached: **49**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
In this study patients who met inclusion criteria were divided into intervention and control group by simple randomization method.This method is one of basic methods for sampling in experimental studies, and frequently is used in studies with a few sample size.For randomization between two groups, random numbers table is used.In this study fifty patients with diagnosis of CABG in Heart surgery critical care unit of Ayatollah Mousavi hospital after matching for demographic data's and Apache 2 Score we're divided into intervention group and control group by randomization with computerized random number tables.Fifty random numbers were extracted of computer by using random number table and for example 24th sample was set in intervention group and 14th sample was set in control group and this process was performed until end of the study.
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Zanjan University of Medical Sciences
**Street address**
Azadi Blvd, Zanjan
**City**
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**Province**
Zanjan
**Postal code**
4515613191
**Approval date**
2013-04-28, 1392/02/08
**Ethics committee reference number**
2/92-328-04

## Health conditions studied

### 1

**Description of health condition studied**
Cardiac coronary arterial disease
**ICD-10 code**
I27.9
**ICD-10 code description**
I26-I28

## Primary outcomes

### 1

**Description**
The ratio of partial pressure arterial oxygen and fraction of inspired oxygen(Pao2/Fio2)
**Timepoint**
The time points of blood sampling were after induction, before the administration of N-acetylcysteine (NAC) (pre-CPB)(Time 1) as baseline, one hour after CPB (on-CPB)(Time 2) , and one hour after that the patients were off-CPB (post-CPB)(Time 3).
**Method of measurement**
Pao2/Fio2 measurement kit was used to measure Pao2/Fio2 by atrial blood gas machine.

### 2

**Description**
Alveolar–arterial (A-a) gradient
**Timepoint**
The time points of blood sampling were after induction, before the administration of N-acetylcysteine (NAC) (pre-CPB)(Time 1) as baseline, one hour after CPB (on-CPB)(Time 2) , and one hour after that the patients were off-CPB (post-CPB)(Time 3).
**Method of measurement**
A-a gradient measurement kit was used to measure A-a gradient by atrial blood gas machine.

**3**

**Description**
Interleukin-6
**Timepoint**
The time points of blood sampling were after induction, before the administration of N-acetylcysteine (NAC) (pre-CPB)(Time 1) as baseline, one hour after CPB (on-CPB)(Time 2) , and one hour after that the patients were off-CPB (post-CPB)(Time 3).
**Method of measurement**
Interleukin-6 measurement kit was used to measure Interleukin-6.

**4**

**Description**
Shunt
**Timepoint**
The time points of blood sampling were after induction, before the administration of N-acetylcysteine (NAC) (pre-CPB)(Time 1) as baseline, one hour after CPB (on-CPB)(Time 2) , and one hour after that the patients were off-CPB (post-CPB)(Time 3).
**Method of measurement**
Using the formula used to measure it.

**5**

**Description**
Compliance reactive protein (CRP)
**Timepoint**
The time points of blood sampling were after induction, before the administration of N-acetylcysteine (NAC) (pre-CPB)(Time 1) as baseline, one hour after CPB (on-CPB)(Time 2) , and one hour after that the patients were off-CPB (post-CPB)(Time 3).
**Method of measurement**
Compliance reactive protein (CRP) measurement kit was used to measure Compliance reactive protein (CRP).

**6**

**Description**
CKMB
**Timepoint**
The time points of blood sampling were after induction, before the administration of N-acetylcysteine (NAC) (pre-CPB)(Time 1) as baseline, one hour after CPB (on-CPB)(Time 2) , and one hour after that the patients were off-CPB (post-CPB)(Time 3).
**Method of measurement**
Creatine kinase-muscle/brain (CKMB) measurement kit was used to measure creatine kinase-muscle/brain (CKMB).

**7**

**Description**
Troponine
**Timepoint**
The time points of blood sampling were after induction, before the administration of N-acetylcysteine (NAC) (pre-CPB)(Time 1) as baseline, one hour after CPB (on-CPB)(Time 2) , and one hour after that the patients were off-CPB (post-CPB)(Time 3).
**Method of measurement**
Troponine measurement kit was used to measure Troponine.

**8**

**Description**
Serum Lactate
**Timepoint**
The time points of blood sampling were after induction, before the administration of N-acetylcysteine (NAC) (pre-CPB)(Time 1) as baseline, one hour after CPB (on-CPB)(Time 2) , and one hour after that the patients were off-CPB (post-CPB)(Time 3).
**Method of measurement**
Lactate measurement kit was used to measure Lactate.

**9**

**Description**
Creatinine
**Timepoint**
The time points of blood sampling were after induction, before the administration of N-acetylcysteine (NAC) (pre-CPB)(Time 1) as baseline, one hour after CPB (on-CPB)(Time 2) , and one hour after that the patients were off-CPB (post-CPB)(Time 3).
**Method of measurement**
Creatinine measurement kit was used to measure Creatinine.

**10**

**Description**
Ejection fraction
**Timepoint**
The time points of blood sampling were after induction, before the administration of N-acetylcysteine (NAC) (pre-CPB)(Time 1) as baseline, and one hour after that the patients were off-CPB (post-CPB)(Time 3).
**Method of measurement**
Using the formula used to measure it.

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: After induction, a central venous line was inserted and first blood sample (pre-CPB time) was obtained. After this stage, the NAC group received 100 mg/kg NAC.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: the control group received normal saline one hour before initiating CPB.
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Ayatollah Mousavi hospital
**Full name of responsible person**
Mohammadreza Jamshidi
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Ayatollah Mousavi Hospital, Sobotie Blvd, Zanjan
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## Sponsors / Funding sources

**1**

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http://zums.ac.ir/index.php?slc_lang=fa&sid=3
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Zanjan University of Medical Sciences
**Proportion provided by this source**
50
**Public or private sector**
Private
**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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Zanjan University of Medical Sciences
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**Position**
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**Latest degree**
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**Other areas of specialty/work**
Anesthesiology
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## Person responsible for scientific inquiries

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
Yes - There is a plan to make this available
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
Yes - There is a plan to make this available
**Data Dictionary**
Yes - There is a plan to make this available
**Title and more details about the data/document**
After completing the study, there is a plan to share non-identifiable individual data of the participants, the study protocol, the statistical analysis of the data, the informed consent form patents, clinical reports, analysis codes, and data coding systems (Dictionary).
**When the data will become available and for how long**
The start of the access period to the data of this study will be from mid-2019 and approximately 6 months after the publication of the results
**To whom data/document is available**
The data from this study will be available to all people who can play a role in caring for CABG patients, such as families, and healthcare workers.
**Under which criteria data/document could be used**
The researcher tend to use data to improve patients, especially CABG patients.
**From where data/document is obtainable**
To receive information anyone can be use the following email: jamshidianes@zums.ac.ir
**What processes are involved for a request to access data/document**
The data will be sent to the applicants after her introduction and the reason for the need for data.
**Comments**