

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

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 912 334 6346

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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

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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

Street address

Ayatollah Mousavi Hospital, Sobotie Blvd, Zanjan

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

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Web page address

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

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Mohammadreza Jamshidi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Mohammadreza Jamshidi

Position

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Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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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

Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

azarakhsh Barbod

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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