Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of intravenous N-acetylcysteine on prevention of atrial fibrillation after Coronary Artery Bypass Graft surgery(CABG)

Protocol summary

Summary

One of the common complications after coronary artery bypass surgery (CABG) is arrhythmia. The most common arrhythmia in this patients is atrial fibrillation (AF). Postoperative AF can lead to hemodynamic instability, palpitation, thromboembolism, higher risk of stroke after surgery, increase length of intensive care unit (ICU) stay and consequently increased costs . So far there have been many efforts to reduce the incidence of AF in these high risk patients. In recent years, several studies have demonstrate the role of inflammation and oxidative stress in the pathogenesis of postoperative AF. Therefore, to prevent it they recommend the use of antioxidant and anti-inflammatory agents. In such cases, one of the drugs which has been used used is N-acetylcystein (NAC). It has antioxidant and anti-inflammatory properties. There are only few studies about the effects of NAC on prevention of post-operative AF after CABG, with conflicting results. This study aimed to evaluate the effects of NAC on prevention of AF after CABG surgery to reduce the incidence of this arrhythmia and its complications, consequently reduce the costs of patients hospital stay. This study is a randomized double-blinded clinical trial. Participants of this study are patients who will admit in the Mazandaran heart center for elective CABG surgery. After taking essential agreements, we will select 150 patients using randomized numerous schedule. In the intervention group, after induction of anesthesia, we will infuse 50 mg/kg NAC in 30 minutes and repeat it every day for two days after surgery. We will use normal saline infusion as placebo in the control group, in the same time interval. In addition, before and 3 days after surgery a blood sample is taken to assess serum hsCRP level. All patients will be evaluated for occurrence of any postoperative AF. Also other variables including length of ICU and hospital stay will be assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015040921669N1**
Registration date: **2016-09-12, 1395/06/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-09-12, 1395/06/22

Registrant information

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Aria Soleimani
Name of organization / entity
Mazandaran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Mazandaran Universiy of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of intravenous N-acetylcysteine on prevention of atrial fibrillation after Coronary Artery Bypass Graft surgery(CABG)

Public title
Effect of intravenous N-acetylcysteine on prevention of atrial fibrillation after Coronary Artery Bypass Graft surgery(CABG) .

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: Patient's willingness to participate in the study and getting informed consent from them; Non-emergency CABG surgery; Using cardiopulmonary bypass pump; No history of cardiac tachyarrhythmias before surgery (including AF); Having sinus rhythm; Hemodynamic stability (50 MAP> and heart rate between 50-110); and age between 35 and 75 years. Exclusion criteria: Heart failure patients with ejection fraction (EF) less than 30%; History of COPD, Hyperthyroidism; Occurrence of postoperative MI; Need to pacemaker post-operatively; Re-operation for any reason; Previous history of heart surgery; Use of anti-arrhythmic drugs (with the exception of beta-blockers); Using Inotropic drugs more than the usual dose (epinephrine infusion more than 0.1 mcg / kg / min and dopamine and dobutamine infuson more than 10 mcg / kg / min)

Age
From **35 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mazandaran University of Medical Sciences

Street address
Sari, Moalem Square

City
Sari

Postal code
4818813771

Approval date
2013-09-11, 1392/06/20

Ethics committee reference number
1392-6-20

Health conditions studied

1

Description of health condition studied
Atrial Fibrillation

ICD-10 code
148

ICD-10 code description
Atrial fibrillation and flutter

Primary outcomes

1

Description
Postoperative Atrial Fibrillation

Timepoint
72 hours after surgery and continued after discharge from the ICU

Method of measurement
By the senior nurse in open heart surgical intensive care unit prosperity and approved by the monitoring device by cardiologists

Secondary outcomes

1

Description
Serum hsCRP

Timepoint
Preoperative and postoperatively in the first and third day

Method of measurement
With Elisa method and using Vidas

Intervention groups

1

Description
Double blind clinical trial

Category
Treatment - Drugs

2

Description
In the intervention group, 50 mg of N-acetylcysteine will

be administered intravenously during the procedure, 24 and 48 hours after surgery, within 30 minutes.

Category

Treatment - Drugs

3

Description

In the control group, patients will receive intravenous infusion of normal saline as placebo, intra-operatively and also 24 and 48 hours after surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Zahra Hospital

Full name of responsible person

Dr. Aria Soleimani

Street address

Fatemeh Zahra Hospital, artesh BLVD

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Ahmadali Enayati

Street address

Mazandaran Heart Center, artesh BLVD

City

Sari

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Aria Soleimani

Position

Assistant Professor Anesthesia

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty