

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Effect of N-acetylcysteine on prevention of postcardiac surgery atrial fibrillation

Protocol summary

Summary

Postoperative atrial fibrillation (AF) is the most frequent arrhythmia after cardiac surgery. It is associated with cerebrovascular accidents, hypotension, pulmonary oedema, longer hospital stays, increased cost of the procedure, and mortality. A total of 240 consecutive patients undergoing cardiac surgery in our centre between February 2010 and April 2010 were screened for eligibility. To be included in the study, patients needed to be referred for primary elective coronary artery and/or valve surgery, 18 years of age and in normal sinus rhythm. Exclusion criteria included prior coronary revascularization or heart valve surgery, emergency surgery, New York Heart Association class III or IV congestive heart failure, history of AF, hyperthyroidism, inflammatory diseases except coronary artery disease, infection, a left atrium size >70 mm, electrolyte imbalance, age >18 years old, and ejection fraction <0.25 . The aim of this prospective, randomized, double-blind, placebo controlled study was to assess the effects of in the prevention of the postoperative AF. Patient take NAC from 48 before till 72 hours after surgery and control group take placebo . After completion of the surgical procedure, patients were admitted to the intensive care unit and when their haemodynamic and respiratory functions were stable, they were transferred to the wards. Rhythm was monitored continuously during the operation and during the first 2 postoperative days in the intensive care unit.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008134561N1**

Registration date: **2011-05-29, 1390/03/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-05-29, 1390/03/08

Registrant information

Name

Kamran Ghasemi

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Cardiac research center of Tabriz university of medical sciences

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2011-04-21, 1390/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of N-acetylcysteine on prevention of postcardiac surgery atrial fibrillation

Public title

Effect of N-acetylcysteine on prevention of postcardiac surgery atrial fibrillation

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: primary elective coronary artery and/or valve surgery, older than 18 years of age in normal sinus rhythm. Exclusion criteria: prior coronary revascularization or heart valve surgery, emergency surgery, New York Heart Association class III or IV congestive heart failure, history of AF, hyperthyroidism, inflammatory diseases except coronary artery disease, infection, a left atrium size 70 mm, electrolyte imbalance, and ejection fraction 0.25

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **240**

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
Tabriz University of Medical Sciences

Street address
Daneshgah St

City
Tabriz

Postal code
5166615573

Approval date
2010-05-29, 1389/03/08

Ethics committee reference number
5/4/1604

Health conditions studied

1

Description of health condition studied
Atrial fibrillation

ICD-10 code

I48

ICD-10 code description

Atrial fibrillation and flutter

Primary outcomes

1

Description

Postoperative atrial fibrillation

Timepoint

before and up to 48h after surgery

Method of measurement

ECG holtermonitoring

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group take 1200mg tab q12h NAC from 48 before till 72 hour after surgery

Category

Prevention

2

Description

Control group take placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Hospital

Full name of responsible person

Babak Kazemi

Street address

Imam Khomeini St. Daneshgah St. Near Imam Khomeini Hospital

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Cardiac Research Center of Tabriz Universityof Medical sciences

Full name of responsible person

Babak Kazemi

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Imam Khomeini St, Daneshgah St, Near Imam
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Grant name

105006

Grant code / Reference number**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Cardiac Research Center of Tabriz 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**

Cardiac Research Center of Tabriz University of
Medical Sciences

Full name of responsible person

Babak Kazemi

Position

Cardiologist

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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