

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the effect of N-acetylcysteine plus carvedilol, with carvedilol alone, in the prevention of atrial fibrillation after open heart surgery

Protocol summary

Summary

Since there is no successful prophylactic strategy in preventing atrial fibrillation after open heart surgery, In this study, we compared the effect of N-acetylcysteine plus carvedilol, with carvedilol alone, on prophylaxis of atrial fibrillation after cardiac surgery in patients undergoing open heart surgery. For all of patients who have been candidated for CABGs surgery and referred to Fateme Zahra Hospital, carvedilol prescribed from 3 days before surgery. Unless who have contraindicated for taking Bblocker (such as bradycardia, advanced AV block chronic obstructive pulmonary disease) and patients who have prior AF or condidated for valvular surgery. A total number of 300 cases (from 21 to 81 years old) (150 in case & 150 in control group) during 1393-1394 who underwent CABG in Fateme Zahra Hospital. Both groups have taken carvedilol from 3 days before CABG and in case groups after in time of bypassing, 4 mmol/lit NAC was added to cardioplegic solution for cardiac arrest whereas equal volume of N/S added to control group all of the patients were monitored 5 day after the surgery and incidence of atrial fibrillation was recorded in two groups. . Finally, we compared the effect of N-acetylcysteine in reducing the incidence of atrial fibrillation after open heart surgery in the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012100611013N1**

Registration date: **2017-08-26, 1396/06/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-08-26, 1396/06/04

Registrant information

Name

Rozita Jalalian

Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences- Fatemeh Zahra Hospital

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-09-30, 1395/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of N-acetylcysteine plus carvedilol, with carvedilol alone, in the prevention of atrial fibrillation after open heart surgery

Public title

Comparison of the effect of N-acetylcysteine plus carvedilol, with carvedilol alone, in the prevention of atrial fibrillation after open heart surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: All patients who were underwent CABG surgery in Fatemeh Zahra Hospital. Exclusion criteria: Contraindication for Beta Blocker; COPD; Advanced AV block; Previous AF rhythm; HR<60; SBP<90 mmHg; CABG + MVR/AVR; CABG + MV repair

Age

From **21 years** old to **81 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not 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

Three Joibar

City

Sari

Postal code

Approval date

2016-08-09, 1395/05/19

Ethics committee reference number

IR.MAZUMS.REC.95.2026

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

Atrial Fibrillation

Timepoint

Since the beginning until the completion of data collection

Method of measurement

VAS Monitor

Secondary outcomes

1

Description

Duration of intubation

Timepoint

post CABG

Method of measurement

time recording in file

Intervention groups

1

Description

Case group:All of patients who are candidated for open heart surgery and didn't have contraindication for Beta blocker underwent premedication with oral carvedilol with doses 6.25 mg twice days for 3 days before open heart surgery, In these patients, at the time of initiation of cardiopulmonary bypass and when using a cardiopulmonary solution for cardiac arrest, n-acetylcysteine at a rate of 4 millimole per liter (50 mg / kg) was added to the second cardioplegic solution in a single dose, and Eventually, the solution is used during the operation on the heart tissue.and they are monitored for five days in the intensive care unit.

Category

Prevention

2

Description

Control group:All of patients who are candidated for open heart surgery and didn't have contraindication for Beta blocker underwent premedication with oral carvedilol with doses 6.25 mg twice days for 3 days before open heart surgery For this patients,after initiation of cardiopulmonary bypass,equal volume of normal saline solution added to cardioplegic solution and The obtained solution was used without any extra material on the heart tissue during surgery.and they are monitored for five days in the intensive care unit.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Zahra Hospital

Full name of responsible person

Dr. Rozita Jalalian

Street address

Artesh BLVD- Fatemeh Zahra Hospital

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

Moallem Street

City

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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

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 Rozita Jalalian

Position

Assistente Professor/Flowship Echocardiography

Other areas of specialty/work

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Position

Assistente Professor- Flowship Echocardiography

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Dr Mahsa Maleki

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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