Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 reffered 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
Country
Iran (Islamic Republic of)
Phone
+98 15 1222 4002
Email address
rjalalian@mazums.ac.ir

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 milimole 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 salin 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
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 Rozita Jalalian
Position
Assistante Professor/Flowship Echocardiography
Other areas of specialty/work
Street address
Artesh BLVD- Mazandaran Heart Center
City
Sari
Postal code
4818813771
Phone
+98 11 3332 4002
Fax
Email
rozitajalalian@yahoo.com; mahsa_maleki4478@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical sciences
Full name of responsible person
Dr Rozita Jalalian
Position
Assistante Professor- Flowship Echocardiography
Other areas of specialty/work
Street address
Artesh BLVD- Mazandaran Heart Center
City
Sari
Postal code
4818813771
Phone
+98 11 3332 4002
Fax
Email
rjalalian@mazums.ac.ir; rozitajalalian@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr Mahsa Maleki
Position
Resident of Cardiology
Other areas of specialty/work
Street address
Artesh BLVD- Mazandaran Heart Center
City
Sari
Postal code
4818813771
Phone
+98 11 3332 4002
Fax
Email
mahsa_maleki4478@yahoo.com
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