Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Comparing therapeutic effects of carvedilol and metoprolol in prevention of atrial fibrillation after coronary artery bypass surgery, double blinded study

Protocol summary

Summary

This clinical trial compares the preventive effect of carvedilol and metoprolol on occurrence of AF after CABG surgery. Study population is going to include 150 patients (55 women, 95 men; mean age: 59±10) who are going to perform CABG surgery. Patients with no contraindication for β-blocker use are going to randomly assign into two groups of Carvedilol and Metoprolol (n=75). Treatment with β-blocker is going to start on the first postoperative day (metoprolol, 25 mg BD; carvedilol, 6.25 mg, BD) and the dosage will regulate according to the patients' hemodynamic response. All patients will monitor 5 days after the surgery and incidence of AF and other complications will record in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013111015178N2**
Registration date: **2014-01-03, 1392/10/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-01-03, 1392/10/13

Registrant information

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing therapeutic effects of carvedilol and metoprolol in prevention of atrial fibrillation after coronary artery bypass surgery, double blinded study

Public title

therapeutic effects of Carvidelol and Metoprolol in prevention of cardiac arrhythmia after open heart surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients indicated for CABG surgery who did not have any contraindications for beta blocker use .Exclusion criteria: chronic obstructive respiratory failure; advanced AV block; previous AF; bradycardia (HR<60); hypotension (SBP<90); ejection fraction<35%; patients who were undergoing repair or replace of heart valve along with their CABG surgery.

Age

From **21 years** old to **81 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
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
Juybar Interaction
City
Sari
Postal code
Approval date
2012-12-19, 1391/09/29
Ethics committee reference number
29/9/91

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
During the first 5 days after CABG
Method of measurement
Cardiac monitoring

Secondary outcomes

1

Description
Ventricular fibrillation
Timepoint
During the first 5 days after CABG in ICU
Method of measurement
Cardiac monitoring

Intervention groups

1

Description
A total of 150 patients 75 in each drug group, enroll in the study.Initiative dose is going to be 25 mg/BD in metoprolol group and will increase according to the patients' hemodynamic responses.Cardiac monitoring going to performe in patients during ICU and 5 days post-ICU
Category
Prevention

2

Description
A total of 150 patients 75 in each drug group, enroll in the study.Initiative dose is going to be 6.25 daily in carvideloll group and increase according to the patients' hemodynamic responses.Cardiac monitoring is going to performe in patients during ICU and 5 days post-ICU
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Mazandaran Heart Center
Full name of responsible person
Street address
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Rozita Jalalian
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University Building, Juybar Interaction, Imam Square

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

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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