

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

Name

Rozita Jalalian

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 1219 9591

Email address

r.jalalian@mubabol.ac.ir

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 carvedilol 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

Street address

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

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Rozita Jalalian
Position
Assistant Professor of cardiology
Other areas of specialty/work
Street address
Mazandaran Heart Center, Artesh BLVD
City
Sari
Postal code
Phone
+98 15 1222 4002
Fax
Email
rozita_jalalian@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
Rozita Jalalian
Position

Assistant Professor of cardiology
Other areas of specialty/work
Street address
Mazandaran Heart Center, Artesh BLVD
City
Sari
Postal code
Phone
+98 15 1222 4002
Fax
Email
rozita_jalalian@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
Rozita Jalalian
Position
Assistant professor of cardiology
Other areas of specialty/work
Street address
mazandaran Heart Center, Artesh BLVD
City
Sari
Postal code
Phone
+98 15 1222 4002
Fax
Email
rozita_jalalian@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