

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The comparison of metoprolol and carvedilol in prevention of AF after CABGS

Protocol summary

Study aim

Comparison of the effect of carvedilol and metoprolol on the incidence of AF after cardiac surgery in patients undergoing open heart surgery in Imam Ali Hospital in 1997

Design

To assign people to two groups, randomization is done by blocking method, which each intervention patient receives. As such, 6 blocks of 4 are provided as follows.1) AABB 2) ABAB 3) ABBA 4) BBAA 5) BABA 6) BAAB Block selection is based on the random number table. Group A patients receiving metoprolol and B patient receiving carvedilol.

Settings and conduct

In this study, double blind blindness is used so that the patient and the investigator who applies the interventions are not aware of the interventions. . After transferring patients to the department, monitoring of the 24-hourly electrocardiogram will be performed for five days

Participants/Inclusion and exclusion criteria

. The criteria for entering the study will be all patients who undergo cardiac surgery due to coronary artery disease or valvular abnormalities, preoperative beta-blocker therapy (propranolol, metoprolol, carvedilol for heart rate of 60 to 70 Minutes) and obtaining written consent, patients with prior history of atrial fibrillation, receive class I, II antiarrhythmic drugs, digoxin, permanent or temporary pacemakers, each grade from the heart block, bradycardia with heart rate less than 50, end-stage renal disease (ESRD) , Severe pulmonary disease (pneumonia, COPD) and severe liver disease (cirrhosis or hepatitis folinitis) They will not be included in the study.

Intervention groups

In this randomized clinical trial, patients undergoing non-emergency open heart surgery candidates admitted to Ali ibn Abitaleb Zahedan Hospital will be divided into two groups of metoprolol, carvedilol to prevent the onset of

AF.

Main outcome variables

AF incidence in patients after open heart surgery

General information

Reason for update

Acronym

AFCABG

IRCT registration information

IRCT registration number: **IRCT20181110041604N1**

Registration date: **2019-04-13, 1398/01/24**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-13, 1398/01/24**

Update count: **0**

Registration date

2019-04-13, 1398/01/24

Registrant information

Name

aylar ghavanjzade

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3329 4209

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of metoprolol and carvedilol in prevention of AF after CABGS

Public title

The comparison of metoprolol and carvedilol in prevention of AF after CABGS

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The criteria for entry into the study will be all patients who undergo cardiac surgery due to coronary artery disease or valvular disorders

Exclusion criteria:

Previous history of atrial fibrillation Receiving class I, II antiarrhythmic drugs Digoxin Permanent or temporary pacemaker Each grade of the heart block - Bradycardia with heart rate less than 50 Dialysis patients Severe pulmonary disease Heavy liver disease

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **170**

Randomization (investigator's opinion)

Randomized

Randomization description

To assign people to two groups, randomization is done by blocking method, which each intervention patient receives. As such, 6 blocks of 4 are provided as follows. 1) AABB 2) ABAB 3) ABBA 4) BBAA 5) BABA 6) BAAB Block selection is based on the random number table. Group A patients receiving metoprolol and B patient receiving cartidilol.

Blinding (investigator's opinion)

Double blinded

Blinding description

To assign people to two groups, randomization is done by blocking method, which each intervention is receiving. Patients and physicians are not aware of blind blindness. Block selection is based on the random number table. Group A patients receiving metoprolol and B patient receiving carvedilol.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Zahedan University of Medical Sciences

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Imam Ali Hospital ,Khalij Fars Blvd

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Zahedan

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Sistan-va-Balouchestan

Postal code

9817959515

Approval date

2019-01-30, 1397/11/10

Ethics committee reference number

IR.ZAUMS.REC.1397.250

Health conditions studied**1****Description of health condition studied**

AF

ICD-10 code

I48.0

ICD-10 code description

Paroxysmal atrial fibrillation

Primary outcomes**1****Description**

AF after surgery

Timepoint

5 days after surgery

Method of measurement

ECG

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients who receive metoral

Category

Treatment - Drugs

2

Description

Intervention group: Patients receiving carvedilol

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali hospital Zahedan

Full name of responsible person

Aylar Ghavanjzade

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Deputy of Research of Zahedan University of Medical Sciences-Dr Shahraki

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Web page address

<http://Zaums.ac.ir/default.page>

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

Yes

Title of funding source

Zahedan University of Medical Sciences

Proportion provided by this source

20

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Aylar.Ghavanjzade

Position

Resident

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available