

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of oral Bisoprolol in comparison with oral Metohexall in prevention of atrial fibrillation in coronary artery bypass graft (CABG)

Protocol summary

Study aim

Evaluation of the effect of oral bisoprolol in comparison with oral metohexal in the prevention of atrial fibrillation in patients with coronary artery surgery

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 114 patients. Excel software rand function was used for randomization

Settings and conduct

A double-blind randomized trial to be performed at Qazvin University of Medical Sciences' Bouali Hospital. The drugs will be distributed by a pharmacology department that also specializes in random codes, and researchers and patients will be blind to this allocation. Doctors who also interpret electrocardiograms will also be blind to the allocation of blind patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria All patients who are candidates for CABG surgery in Bo Ali Hospital in Qazvin will be included in the study if there are no exclusion criteria, except for those who have exclusion criteria. Exclusion criteria: 1. History of previous atrial fibrillation 2- Having a permanent pacemaker 3- Any conclusive or possible evidence of having any type of ventricular or supra ventricular arrhythmia 4. The size of the left ventricle 5. Moderate to severe heart valve disease 6. miocardial infarction 7. Lung disease

Intervention groups

In the control group, methotrexate tablets and in the control group, bisoprolol tablets are administered 48 hours before surgery and up to 4 days after surgery in two separate groups. If beta-blocker is indicated, the drug is continued, otherwise the drug is discontinued.

Main outcome variables

atrial fibrillation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210121050095N1**

Registration date: **2021-05-19, 1400/02/29**

Registration timing: **retrospective**

Last update: **2021-05-19, 1400/02/29**

Update count: **0**

Registration date

2021-05-19, 1400/02/29

Registrant information

Name

Saeid Negahdar hadadan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 2930

Email address

s.negahdar@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-26, 1399/06/05

Expected recruitment end date

2021-03-02, 1399/12/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral Bisoprolol in comparison with oral Metohexall in prevention of atrial fibrillation in coronary artery bypass graft (CABG)

Public title

Evaluation of the effect of bisoprolol in the control of atrial fibrillation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with coronary heart disease are candidates for coronary heart surgery

Exclusion criteria:

History of previous atrial fibrillation Having a permanent pacemaker Any conclusive evidence of any ventricular or supra ventricular arrhythmia Large left ventricle Moderate to severe valvular heart disease myocardial infarction Lung disease

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be assigned to two groups using a simple random method. Bisoprolol will be assigned to the first group and methohexal will be prescribed to the second group They will be.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blind. and researchers and patients were blind to this allocation. Doctors who also interpret electrocardiograms will be blind to the allocation of patients. After completing the study and collecting the results, the relevant codes will be provided to each patient team and the method of performing the double-blind nature of the study was such that neither the patient nor the researcher were aware of patient allocation. They were similarly packaged to avoid identification

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

No.16,badr st Eats,8th Alley

City

Qazvin

Province

Qazvin

Postal code

3471853318

Approval date

2020-08-24, 1399/06/03

Ethics committee reference number

IR.QUMS.REC.1399.063

Health conditions studied

1

Description of health condition studied

Atrial fibrillation in patients undergoing coronary artery bypass grafting

ICD-10 code

I48

ICD-10 code description

Atrial fibrillation and flutter

Primary outcomes

1

Description

Incidence of atrial fibrillation after coronary artery surgery

Timepoint

Up to four days after coronary artery surgery

Method of measurement

How to diagnose and measure atrial fibrillation using ECG based on p's presence and irregularity of QRS and QRS count

Secondary outcomes

empty

Intervention groups

1

Description

Intervention. Patients received bisoprolol orally with the initial dose 2.5 mg one day before surgery to 3 days postoperatively based on heart rate, blood pressure, and ECG.

Category

Treatment - Drugs

2

Description

Control group: Patients received methohexal at an initial dose of 23.75 mg orally one day before surgery to 3 days postoperatively based on heart rate, blood pressure, and ECG.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin University of Medical Sciences Bo Ali Hospital

Full name of responsible person

Saeid negahdar hahdadan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Mohammad Mehdi Imam Juma

Street address

Shahid Beheshti Blvd. - Movadat Sub-Department of Research and Technology, Qazvin University of Medical Sciences

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research.dpt@qums.ac.ir

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Qazvin University of Medical Sciences

Proportion provided by this source

100

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

Qazvin University of Medical Sciences

Full name of responsible person

Saeid Negahdar hadadan

Position

Cardiovascular Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After coding and unidentifiable, patients are shared based on the main consequences associated with the disease

When the data will become available and for how long

Start access valley one year after printing results

To whom data/document is available

Researchers at General Medical Universities

Under which criteria data/document could be used

For scientific exploitation

From where data/document is obtainable

Saeid Negahdar Hadadan/S.negahdar@qums.ac.ir

What processes are involved for a request to access data/document

Send an email explaining the reason for the request

Comments