Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 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

Street address
Naderi St., Bo ali Hospital

City
Qazvin

Province
Qazvin

Postal code
3413786165

Phone
+98 28 3332 6032

Fax
+98 28 3334 2009

Email
dr.negahdar@gmail.com

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

City
Qazvin

Province
Qazvin

Postal code
3419915315

Phone
+98 28 3333 7006

Email
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

Street address
Gazvin minodar badar shargi

City
Gazvin

Province
Qazvin

Postal code
3419915315

Phone
+98 28 3333 2930

Fax

Email
S.negahdar@qums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Saeid Negahdar hadadan

Position
Cardiovascular Assistant

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Postal code
3419915315
Phone
+98 28 3333 2930
Fax
Email
S.negahdar@qums.ac.ir

Person responsible for updating data

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
Street address
Gazvin minodar badar shargi
City
Gazvin
Province
Qazvin
Postal code
3419915315
Phone
+98 28 3333 2930
Fax
Email
S.negahdar@qums.ac.ir

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