Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Evaluation of the effect of oral sotalol in comparison with oral metoprolol succinate in prevention of atrial fibrillation in patients after coronary artery bypass graft surgery

Protocol summary

Study aim

Evaluation of the effect of oral sotalol in comparison with oral metoprolol succinate in prevention of atrial fibrillation in patients after coronary artery bypass graft surgery

Design

This clinical trial has 2 intervention groups, double-blind, 188 candidates for CABG are randomly divided into two groups using the law of random assignment. each of the selected people will be assigned a numerical order from 1 to 188. then a random sequence will be considered to include people in the study by using the Statistics and Sample Size software.

Settings and conduct

All patients candidates for CABG surgery in BoAli Qazvin Hospital are included in the study. The consent form is given to the patients upon arrival. Demographic information is recorded on the first day of hospitalization. Preventive treatment for atrial fibrillation rhythm following surgery is metoprolol succinate in one group and sotalol in the other group. Sotalol and metoprolol succinate were prescribed to all patients from a specific pharmaceutical company. If AF occurs, sotalol is stopped and another appropriate beta-blocker is started for the patient along with amiodarone. If the patient has already been treated with a beta-blocker, after the end of the sotalol administration period, the previous beta-blocker should be continued with the appropriate dose.

Participants/Inclusion and exclusion criteria

All patients candidates for CABG surgery

Intervention groups

Metoprolol succinate and sotalol tablets are prescribed 24 hours before surgery and up to 3 days after surgery in 2 separate groups. Sotalol is started at a dose of 40 mg daily and metoprolol succinate at a dose of 47.5 mg per day and is adjusted according to the patient's heart rate. The prescribed dose is adjusted based on the patient's clinical response and the patient's heart rate is maintained at 55-60.

Main outcome variables

incidence of atrial fibrillation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231123060154N1**
Registration date: **2023-12-03, 1402/09/12**
Registration timing: **prospective**

Last update: **2023-12-03, 1402/09/12**
Update count: **0**

Registration date

2023-12-03, 1402/09/12

Registrant information

Name

Hadi Naderi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3422 2484

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naderihd@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-04-20, 1403/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral sotalol in comparison with oral metoprolol succinate in prevention of atrial fibrillation in patients after coronary artery bypass graft surgery

Public title

Comparison of the effect of oral sotalol and oral metoprolol succinate in the prevention of atrial fibrillation after coronary artery bypass surgery.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are candidates for CABG

Exclusion criteria:

Previous history of atrial fibrillation Having a permanent pacemaker Any definite or probable evidence of having any type of ventricular or supraventricular arrhythmia Moderate and severe LV enlargement Moderate and severe valvular heart disease acute MI Prolonged QT Patients with severe renal impairment and ESRD Asthma and bronchospasm Patients with hemodynamic disorders and low blood pressure Patients who are taking drugs that interact with sotalol will be excluded from the study if it is not possible to stop the drug. These drugs include: All QT prolonging drugs including: Amiodarone, Amisulpride, Azithromycin, Carbetocin, Ceritinib, Chloroquine, Citalopram, Clarithromycin, Clofazimine, Clomipramine, Clozapine, Dabrafenib, Dasatinib, Domperidone, Doxepine-containing products, Droperidol, Encorafenib, Entrectinib) Nilotinib, Olanzapine, Ondansetron, Osimertinib, Oxytocin, Pacritinib, Pazopanib, Pentamidine, Pilsicainide, Pimozide, Piperaquine, Probucul, Propafenone, Propofol, Quetiapine, Ribociclib, risperidone, Sertindole, Sparfloxacin, Sunitinib, Terbutaline, Thioridazine, Toremifene, Vemurafenib : Alfuzocin, Alpha1- Blockers, Amifostine, Phenothiazines, Barbiturates, Benperidol, Levodpa- Containing products, Lormetazepam, Methoxyflurane, Molsidomine, Naftopidil, Nicergoline, Nicorandil, Nifedipine, Nitroprusside, Obinutuzumab, Pentoxyfilline, Pholcodine, Phosphodiesterase 5 inhibitors, Prostacyclin, Quinagolide, Reserpine: Acetylcholinesterase inhibitors, Ceritinib, Dipyridamole, Etilefrine, Ivabradine, Lacosamide, Midodrine, Ozanimod, Ponesimod, Siponimod, Blood sugar lowering drugs: Insulins, Sulfonylureas, Antidiabetic agents

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **188**

Randomization (investigator's opinion)

Randomized

Randomization description

To implement random allocation, creating a random sequence using the "Random Allocation Law" method will be used. Thus, after determining the sample size, among the people identified in the first stage, several people who meet the criteria for entering the study, are willing to participate in the study and sign the informed consent form, will be selected using the accessible method. In the second stage, each of these selected people will be assigned a numerical order from 1 to 188. In the third step, 188 random sequences created by Statistics and Sample Size software (random numbers without repetition between 1 and 188) will be considered to include people in the study. Each of these numbers will correspond to the number assigned to a person, which is specified in the first list of 188. The numbers will be assigned to the intervention group (prescribing sotalol) and the control group in sequence, and this sequence will be repeated to obtain the desired number of samples for each group. How the random assignment will be performed and to which group the individual will be specialized will not be obvious to the participants.

Blinding (investigator's opinion)

Double blinded

Blinding description

Doctors and researchers collecting data and investigating the outcome and health care personnel will be unaware of the intervention groups. Sotalol and metoprolol succinate drugs have been prepared and will be placed in the hospital without its medicinal properties. Medication packages are prepared by a separate pharmacist. A special code for the type of drug is specified on each package, which identifies it in the study database.

Placebo

Not used

Assignment

Crossover

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

Qazvin University of Medical Sciences, Bahonar boulevard, Ethics committee of Qazvin University of Medical Sciences

City
qazvin

Province
Qazvin

Postal code
59811-34197

Approval date
2023-11-18, 1402/08/27

Ethics committee reference number
IR.QUMS.REC.1402.234

Health conditions studied

1

Description of health condition studied
coronary artery bypass graft

ICD-10 code
I25.7

ICD-10 code description
Atherosclerosis of coronary artery bypass graft(s) and coronary artery of transplanted heart with angina pectoris

2

Description of health condition studied
Atrial fibrillation and flutter

ICD-10 code
I48

ICD-10 code description
Atrial fibrillation and flutter

Primary outcomes

1

Description
Occurrence of atrial fibrillation

Timepoint
Patients are continuously cardiac monitored for atrial fibrillation

Method of measurement
ECG

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Sotalol tablets are prescribed 24 hours before surgery and up to 3 days after surgery. Sotalol is started with a dose of 40 mg per day and is increased or decreased based on the patient's heart rate. The patient's heart rate is maintained at 55-60.

Category
Treatment - Drugs

2

Description
Intervention group: Metoprolol succinate tablets 24 hours before the operation and up to 3 days after the operation with a daily dose of 47.5 mg is decreased or increased based on the patient's heart rate. The prescribed dose is adjusted based on the patient's clinical response and the patient's heart rate is maintained at 55-60.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
BouAli Sina Hospital

Full name of responsible person
hadi naderi

Street address
Bouali Hospital, Bouali Street

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3413786165

Phone
+98 28 3332 6034

Email
naderihd@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Seyed Mahdi Mirhashemi

Street address
Vice-Chancellor's Office for Research and Technology Affairs, Qazvin University of Medical Sciences, Shahid Beheshti Avenue

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Email
sm.mirhashemi@qums.ac.ir

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
hadi naderi
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
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Position
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Latest degree
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All data is potentially shareable after unidentified individuals
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available

Academic and scientific researchers and Industries

Under which criteria data/document could be used

Permission is granted to use the data for meta-analysis or to design other studies

From where data/document is obtainable

ارائه درخواست از طریق ایمیل NADERIHD@GMAIL.COM

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

If the applicant submits a request, if 6 months have passed since the publication of the article, it will be answered in less than 1 week.

Comments