

# 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

##### Email address

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, Piperazine, Probucol, 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, Pentoxifylline, 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

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3413786165

**Phone**

+98 28 3332 6034

**Email**

naderihd@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

**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

**City**

qazvin

**Province**

Qazvin

**Postal code**

34199-15315

**Phone**

+98 28 3333 7006

**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**

Cardiology

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**Person responsible for updating data****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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**Email**

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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**