

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Effect of prophylactic amiodarone in the prevention of postoperative atrial fibrillation after coronary artery bypass surgery in Mazandaran Heart Center

#### Protocol summary

##### Summary

Research: Clinical Trial. Inclusion criterion: preoperative sinus rhythm. Exclusion criteria: allergy to amiodarone or use of amiodarone in the last 6 months; history of toxicity with amiodarone; anti-arrhythmic therapy before surgery; thyroid disease; aspartate aminotransferase or alanine aminotransferase concentration 4 times higher than normal; pregnant patients; a lower rate 50; heart failure; AV block, and surgical history of lung disease and hepatitis. Sample size: 75 double-blind study medication amiodarone and placebo groups, respectively. amiodarone drug, amiodarone vial 2 vials 2 ml ampoules equivalent to 300 mg amiodarone, the incision in the operating room during a time period of 20 minutes through a central venous catheter, and the next dose at 24 hours will receive ICUOH as Drip . Structurally similar to amiodarone and placebo injections and pills. Hospitalized for 7 days after surgery, the patients completed the study per day taken an EKG. Anesthesia in the operating room personnel without being aware of it, measure the length of stay for all patients. Of all patients sampled, measurement of left atrial size and ejection fraction, performed before discharge.

#### General information

##### Acronym

amiodarone

##### IRCT registration information

IRCT registration number: **IRCT2014090813156N7**

Registration date: **2014-12-30, 1393/10/09**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-12-30, 1393/10/09

#### Registrant information

##### Name

Mohammad Ali Heydari Gorji

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 15 1226 7342

##### Email address

mheydarigorji@mazums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Mazandaran University of Medical Sciences

#### Expected recruitment start date

2014-11-22, 1393/09/01

#### Expected recruitment end date

2015-01-21, 1393/11/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of prophylactic amiodarone in the prevention of postoperative atrial fibrillation after coronary artery bypass surgery in Mazandaran Heart Center

#### Public title

Effect of amiodarone in postoperative atrial fibrillation after coronary artery bypass surgery

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criterion: preoperative sinus rhythm. Exclusion

criteria: allergy to amiodarone or use of amiodarone in the last 6 months; history of toxicity with amiodarone, anti-arrhythmic therapy before surgery; thyroid disease; aspartate aminotransferase or alanine aminotransferase concentration 4 times higher than normal; pregnant patients, a lower rate 50; heart failure; AV block and surgical history of lung disease and hepatitis.

**Age**

No age limit

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

No information

**Sample size**

Target sample size: **150**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Mazandaran University of Medical Sciences

**Street address**

Vice chancellor foe research, Mazandaran University of Medical Sciences

**City**

Sari

**Postal code****Approval date**

2014-11-19, 1393/08/28

**Ethics committee reference number**

844

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

CAD in CABG

**ICD-10 code**

T82.2

**ICD-10 code description**

Mechanical complication of coronary artery bypass and

valve grafts

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

The incidence of atrial fibrillation

**Timepoint**

During hospitalization

**Method of measurement**

Monitoring

**Secondary outcomes****1****Description**

Hospitalization time

**Timepoint**

During hospitalization

**Method of measurement**

Monitoring and documentation

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

Control group: in this group use placebo (structured by normal saline serum) that similiar to Amiodarone Ampules and tablets. according to this research, anesthesia and patient do not inform about infusion, so two blind research have. in OR; two times infuse placebo and after that in ICU ward infuse drip in 24 hrs, then oral placebo are fed until discharge. Preoperative and Postoperative atrial size and ejection fraction measured

**Category**

Placebo

**2****Description**

Amiodarone: Amiodarone vial 2 vials 2 ml ampoules equivalent to 300 mg amiodarone, the surgical incision during a time period of 20 minutes through a central venous catheter, and the next dose as Drip ICUOH within 24 hours by weight will receive 20 mg per kg. Preoperative and Postoperative atrial size and ejection fraction measured

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Mazandaran Heart Centre

**Full name of responsible person**

Kaveh Jafari  
**Street address**  
Mazandaran Heart Centre, Sari  
**City**  
Sari

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Research Centre of Mazandaran Univeristy of Medical Sciences  
**Full name of responsible person**  
Dr. Ahmad Ali Enayati  
**Street address**  
Research Centre, moallem square  
**City**  
Sari

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Research Centre of Mazandaran Univeristy of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

*empty*

#### Domestic or foreign origin

*empty*

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Mazandaran University of Medial Sciences  
**Full name of responsible person**  
Kaveh Jafari  
**Position**  
M.Sc  
**Other areas of specialty/work**  
**Street address**  
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## Person responsible for scientific inquiries

#### Contact

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**Full name of responsible person**  
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## Person responsible for updating data

#### Contact

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## Sharing plan

#### Deidentified Individual Participant Data Set (IPD)

*empty*

#### Study Protocol

*empty*

#### Statistical Analysis Plan

*empty*

#### Informed Consent Form

*empty*

#### Clinical Study Report

*empty*

#### Analytic Code

*empty*

#### Data Dictionary

*empty*