Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Name of organization / entity
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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
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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