

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Comparing the efficacy of Amiodarone and Lidocaine in the incidence of cardiac arrhythmia after coronary artery bypass graft surgery

Protocol summary

Summary

Preventing atrial fibrillation is crucial due to decrease any side effect of admission in the hospital. It has been shown that arrhythmia prevention has an important role in decrease mortality and morbidity of patients who undergo cardiac surgery. In this study, we would like to evaluate and compare the preventive effect of Amiodarone and Lidocaine on post CABG cardiac arrhythmia. 150 patients will be randomly assigned (balanced block randomization) to three groups (A, B, and C). In group A: during the cardiopulmonary bypass and before releasing aortic cross clamp, Lidocaine (4 mg/kg) will be added to the prime. In group B and C: during the cardiopulmonary bypass and before releasing aortic cross clamp, Amiodarone (150 mg) and normal saline (5 cc) will be added to the prime, respectively. DC shock will be applied whenever it is required. Na, K, Ca, Mg, PH, and HCO₃ will be evaluated before cross clamping, during CPB time, after release of aortic cross clamp, 1, 6, and 24 hours after entering the ICU. CPK will be evaluated before surgery, 1, 6, and 12 hours after entering the ICU. Outcomes: 1.patients' cardiac rhythm after release of aortic cross clamp, entering the ICU, and entering the ward by holter monitoring.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205198860N2**
Registration date: **2012-05-31, 1391/03/11**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-05-31, 1391/03/11

Registrant information

Name

Alireza Alizadeh Ghavidel

Name of organization / entity

Rajaei Heart Center

Country

Iran (Islamic Republic of)

Phone

+98 21 2392 2147

Email address

aghavidel@rhc.ac.ir

Recruitment status

Recruitment complete

Funding source

Rajaei Heart Center

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2012-11-20, 1391/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of Amiodarone and Lidocaine in the incidence of cardiac arrhythmia after coronary artery bypass graft surgery

Public title

Difference between Amiodarone and Lidocaine in the incidence of arrhythmia after cardiac surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1. Age > 18; 2. patients with coronary artery disease who need CABG surgery; 3. On-pump surgery; 4. In Dr.Ghavidel and Dr.Khamooshi's service; 5.

negative history of ventricular arrhythmia before surgery. Exclusion criteria: 1. Requiring concomitant surgery; 2. Reject to enter to this study; 3. Any known history of sensitivity to Lidocaine or Amiodarone.

Age

From **18 years** old

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)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Rajaei Heart Center

Street address

Valiasr Ave, Niyayesh Blvd

City

Tehran

Postal code

Approval date

2009-08-04, 1388/05/13

Ethics committee reference number

8811248009

Health conditions studied

1

Description of health condition studied

Ischemic Heart Disease

ICD-10 code

I20-I25

ICD-10 code description

Ischemic Heart Disease

Primary outcomes

1

Description

Incidence of cardiac arrhythmia after cardiac surgery

Timepoint

After removal of aortic cross clamp, during ICU stay, during ward stay

Method of measurement

Holter monitoring

Secondary outcomes

1

Description

Mortality rate

Timepoint

30 days after operation

Method of measurement

Interview, phone call

Intervention groups

1

Description

Treatment (A): Lidocaine (4 mg/kg) will be added to the prime before removal of aortic cross clamp

Category

Prevention

2

Description

Treatment (B): Amiodarone (150 mg) will be added to the prime before removal of aortic cross clamp.

Category

Prevention

3

Description

Control (C): Normal saline (5 cc) will be added to the pump solution before removal of aortic cross clamp.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaei Heart Center

Full name of responsible person

Dr. Alireza Alizadeh Ghavidel

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rajaei Heart Center

Full name of responsible person

Dr. Majid Haghjoo

Street address

Valiasr Ave. Nyayesh Blvd.

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Rajaei Heart Center

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**

Rajaei Heart Center

Full name of responsible person

Dr. Alireza Alizadeh Ghavidel

Position

Assistant professor

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Web page address

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