Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the prophylactic effect of amiodarone in reducing the incidence of atrial fibrilation after coronary bypass graft surgery

Protocol summary

Summary

Objectives: Atrial arrhythmia is common in the recovery period in patients with coronary artery bypass graft surgery. Incidence of atrial fibrillation after coronary artery bypass graft surgery increases morbidity and mortality after surgery and also leads to increased length of ICU and hospital stay. Many medications have used to prevent postoperative complications. Amiodarone has antiarrhythmic properties but its use as a prophylactic agent against postoperative incidence of atrial fibrillation is not common and is under discussed. In this study we evaluate the effect of amiodarone in decreasing the incidence of atrial fibrillation after coronary artery bypass graft surgery. Design: Intermittent randomization, double blind, with placebo, including 204 patients candidate for elective coronary artery bypass graft surgery. Participants including major eligibility criteria: All patients candidate for elective coronary artery bypass graft surgery. Intervention: Amiodarone, 300 mg IV infusion over 20-30 minutes and IV infusion within 24 hours after surgery. Main outcome measures: Prevalence of atrial fibrilation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013112215490N1**
Registration date: **2014-01-17, 1392/10/27**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-01-17, 1392/10/27

Registrant information

Name

Niloofar Dadash pour

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences, Vice Chancellor for Research

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2014-07-23, 1393/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the prophylactic effect of amiodarone in reducing the incidence of atrial fibrilation after coronary bypass graft surgery

Public title

effect of amiodarone in reducing the incidence of atrial fibrilation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1. All patients candidate for CABG 2. All patients with ASA II and III. 3. All surveyed patients are candidate for 2 or 3 grafts. Exclusion criteria: 1. Patients candidate for more than 3 grafts. 2. Incidence of any

arrhythmia in placebo group. 3. Incidence of any arrhythmia other than atrial fibrillation in the amiodarone group.

Age
From **35 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **204**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
patients are not aware of administered drug and only the written consent will be obtained. Responsible resident was not aware of the type of drug and drug has been prepared before by the anesthesiologist and would be used by responsible resident according to study group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Arak University of Medical Sciences

Street address
Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran

City
Arak

Postal code

Approval date
2013-09-23, 1392/07/01

Ethics committee reference number
92-149-2

Health conditions studied

1

Description of health condition studied
Atrial fibrillation

ICD-10 code
I48

ICD-10 code description
فیبریلاسیون دهلیزی و فلوتر

Primary outcomes

1

Description
Atrial fibrilation

Timepoint
within 48 hours after surgery

Method of measurement
Cardiac monitoring

Secondary outcomes

empty

Intervention groups

1

Description
Intervention 1. Amiodarone 300 mg intravenous bolus in 30-20 minutes and then 1 mg/kg in first 6 hours after surgery and 0.5 mg/kg IV infusion in next 18 hours.

Category
Treatment - Drugs

2

Description
Intervention 2. Intravenous normal saline as placebo.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Amir al-momenin hospital

Full name of responsible person
Dr Niloofar Dadash pour

Street address
Amir al-momenin hospital. Basij Square. Sardasht. Arak. Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences, Vice Chancellor for Research

Full name of responsible person
Dr Saeed Changizi Ashtiani

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Grant name

Grant code / Reference number

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

Title of funding source
Arak University of Medical Sciences, Vice Chancellor for Research

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
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Position
Anesthsiology resident

Other areas of specialty/work

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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