Evaluation of the prophylactic effect of amiodarone in reducing the incidence of atrial fibrillation 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 fibrillation.

**General information**

**Acronym**

IRCT registration information

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

Last update: empty
Update count: 0
Registration date
2014-01-17, 1392/10/27

**Registrant information**

Name
Niloo far Dadash pour
Name of organization / entity
Arak University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 86 3417 3602
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dr.dadashpour@arakmu.ac.ir

**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 fibrillation after coronary bypass graft surgery

**Public title**

effect of amiodarone in reducing the incidence of atrial fibrillation

**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**
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
فریلابسیون دهلیزی و فلونر

Primary outcomes

1
Description
Atrial fibrillation
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
City
Arak

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
Street address
Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran
City
Arak
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
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**Person responsible for general inquiries**

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<tr>
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<td>Dr Niloofar Dadashpour</td>
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<tr>
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**Person responsible for scientific inquiries**

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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 |