# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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)

**Phone**

+98 86 3417 3602

**Email address**

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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

**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

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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 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**

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Arak University of Medical Sciences

**Full name of responsible person**
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**Position**
Anesthsiology resident

**Other areas of specialty/work**

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## Person responsible for updating data

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**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*