

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

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:

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

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

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 فلوטר

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

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

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 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

Arak University of Medical Sciences

Full name of responsible person

Dr Niloofar Dadash pour

Position

Anesthesiology resident

Other areas of specialty/work

Street address

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

City

Arak

Postal code

Phone

+98 34173505

Fax

Email

ndadashpoor60@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Niloofar Dadash pour

Position

Anesthesiology resident

Other areas of specialty/work

Street address

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

City

Arak

Postal code

Phone

+98 86 3417 3505

Fax

Email

ndadashpoor60@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Niloofar Dadash pour

Position

Anesthesiology resident

Other areas of specialty/work

Street address

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

City

Arak

Postal code

Phone

+98 86 3417 3505

Fax

Email

ndadashpoor60@yahoo.com

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