Clinical Trial Protocol
Iranian Registry of Clinical Trials
12 May 2020

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: 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
فيلیاسیون دهلیزی و فلور

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
Person responsible for general inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Niloofar Dadashpour
Position
Anesthesiology resident
Other areas of specialty/work

Street address
Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran
City
Arak
Postal code
Arak
Phone
+98 3417 3505
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 Dadashpour
Position
Anesthesiology resident
Other areas of specialty/work
Street address
Arak University of Medical Sciences. Basij Square.
City
Arak
Postal code
Arak
Phone
+98 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