

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of prophylactic effect of amiodarone and amiodarone with vitamin c on post CABG atrial fibrillation

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Comparison of prophylactic effect of amiodarone and amiodarone with vitamin c on post CABG atrial fibrillation

Last update: **2018-02-08, 1396/11/19**

Update count: **0**

Registration date

2018-02-08, 1396/11/19

Design

This study is clinical trials and double blind.84 patients with Coronary Artery Bypass Graft Referring to Amiralmomenin Hospital in Arak.

Registrant information

Name

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Name of organization / entity

Arak University of Medical Sciences

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Settings and conduct

This study is clinical trials and double blind.84 patients with Coronary Artery Bypass Graft Referring to Amiralmomenin Hospital in Arak.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with elective CABG; ASA class 2 and 3; Insensitivity to Amiodarone; performing surgery by a surgeon; duration of the surgery is 4 to 6 hours; all patients have normal creatinine Exclusion criteria: going on a cardio-pulmonary pump for 2 times during operation; all patients who die during surgery; Increase the duration of the operation for more than 6 hours; cardiomegaly and CHF; Cardiomyopathy History of cardiac arrest and CPR before surgery

Recruitment status

Recruitment complete

Funding source

Intervention groups

We inject 300 milligram Amiodarine bolus in 10-20 minute in first group after arterline. We inject 150 milligram Amiodarine and 2 gram vitamin C in second group after arterline.

Expected recruitment start date

2017-11-11, 1396/08/20

Expected recruitment end date

2019-11-11, 1398/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Main outcome variables

Comparison of prophylactic effect of amiodarone and amiodarone with vitamin c on post CABG atrial fibrillation

Scientific title

Comparison of prophylactic effect of amiodarone and amiodarone with vitamin c on post CABG atrial fibrillation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N66**

Registration date: **2018-02-08, 1396/11/19**

Public title

Comparison of prophylactic effect of amiodarone and

amiodarone with vitamin c on post CABG atrial fibrillation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with elective CABG ASA class 2 and 3
Insensitivity to Amiodarone Performing surgery by a surgeon
Duration of the surgery is 4 to 6 hours All patients have normal creatinine

Exclusion criteria:

Going on a cardio-pulmonary pump for 2 times during operation All patients who die during surgery Increase the duration of the operation for more than 6 hours
Cardiomegaly and CHF Cardiomyopathy History of cardiac arrest and CPR before surgery

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization with random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient is not aware of the treatment received.
Participant and Analyzer are blind (double blind).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Arak University Of Medical Sciences

Street address

Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3814957558

Approval date

2017-10-29, 1396/08/07

Ethics committee reference number

IR.ARAK.MU.REC.1396.150

Health conditions studied

1

Description of health condition studied

Coronary bypass graft

ICD-10 code

I25.70

ICD-10 code description

Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris

Primary outcomes

1

Description

Arrhythmia atrial fibrillation and other arrhythmia

Timepoint

After treatment

Method of measurement

Count

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We inject 300 milligram Amiodarone bolus in 10-20 minute in first group after arterline.

Category

Treatment - Drugs

2

Description

Intervention group: We inject 150 milligram Amiodarone and 2 gram vitamin C in second group after arterline.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin hospital

Full name of responsible person

Dr Alireza Kamali

Street address

Amiralmomenin hospital, Sardasht

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Email

alikalaliir@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Aliarash Anoshirvani

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Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak

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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

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Bijan Yazdi

Position

Assistant, anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Alireza Kamali

Position

Assistant, Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Samira Yavari

Position

Student of medicine

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal.

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Alireza Kamali

What processes are involved for a request to access data/document

They have to write letters to the professors and the university

Comments