

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of low-dose amiodarone alone and its combination with magnesium in the control of atrial fibrillation after coronary artery bypass graft

Protocol summary

Study aim

Comparison of the effect of low-dose Amiodarone alone and its combination with magnesium in the control of atrial fibrillation after coronary artery bypass graft

Design

The study will be double blind and clinical trial. 208 patients will be randomly divided into 2 groups. The groups are parallel. The trial phase is 3.

Settings and conduct

Patients candidate for coronary artery bypass graft surgery in Amirmomenin Hospital in Arak are divided into 2 groups by simple randomization with envelopes. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: all patients are candidates for coronary artery bypass graft surgery, their surgery is ON Pump, absence of emergency coronary artery bypass graft surgery, lack of valve repair and replacement surgery, insensitivity to Amiodarone and Magnesium. Exclusion criteria: Patients who suffer from cardio-respiratory arrest during surgery and die during surgery, patients who go to the cardiopulmonary pump more than once for any reason.

Intervention groups

Intervention group 1: 300 milligram of Amiodarone is placed on the syringe pump, which is infused for the patient in 20 minutes, and 2 grams of magnesium sulfate will be slowly injected for the patients. Intervention group 2: We will provide only 300 milligram of Amiodarone in the form of infusion for patients.

Main outcome variables

Duration of hospitalization in the intensive care unit, incidence of atrial fibrillation, mortality rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N169**

Registration date: **2021-11-06, 1400/08/15**

Registration timing: **prospective**

Last update: **2021-11-06, 1400/08/15**

Update count: **0**

Registration date

2021-11-06, 1400/08/15

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 86 3222 2003

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of low-dose amiodarone alone and its combination with magnesium in the control of atrial fibrillation after coronary artery bypass graft

Public title

Comparison of the effect of low-dose amiodarone alone and its combination with magnesium in the control of atrial fibrillation after coronary artery bypass graft

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients are candidates for coronary artery bypass graft surgery Their surgery is ON Pump Absence of emergency coronary artery bypass graft surgery Lack of valve repair and replacement surgery Insensitivity to Amiodarone and Magnesium

Exclusion criteria:

Patients who suffer from cardio-respiratory arrest during surgery and die during surgery. Patients who go to the cardiopulmonary pump more than once for any reason.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **208**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be allocated into 2 groups using a permuted balanced block randomization method with the size of blocks 2 and 4. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Random chain concealment is done by opaque envelope method.

Blinding (investigator's opinion)

Double blinded

Blinding description

It is a double-blind study. Analysts, evaluators, and participants are unaware of the consequences of grouping. The intern is unaware of the drugs prescribed in each group and the anesthesiologist prepares the drugs and provides them to the intern, and the patients are not aware of their group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam complex, Basij square, Sardasht, Arak

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3848176941

Approval date

2021-08-29, 1400/06/07

Ethics committee reference number

IR.ARAKMU.REC.1400.134

Health conditions studied

1

Description of health condition studied

Coronary artery bypass graft

ICD-10 code

I25.709

ICD-10 code description

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

Primary outcomes

1

Description

Duration of hospitalization in the intensive care unit

Timepoint

In duration study

Method of measurement

Patient file

2

Description

Incidence of atrial fibrillation

Timepoint

From the beginning of the intervention until 72 hours after the operation

Method of measurement

Physical examination

3

Description

Mortality rate

Timepoint

During the study

Method of measurement

Patient file

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: 300 milligram of Amiodarone is placed on the syringe pump, which is infused for the patient in 20 minutes, and 2 grams of magnesium sulfate will be slowly injected for the patients.

Category

Treatment - Drugs

2**Description**

Intervention group 2: We will provide only 300 milligram of Amiodarone in the form of infusion for patients.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amiralmomenin hospital

Full name of responsible person

Dr Alireza Kamali

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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 Alireza Rostami

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available