Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 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 Amiralmomenin 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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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 comittee of Arak University of Medical Sciences

Street address
Ethics comittee, Research center, Payambar Azam complex, Basij squre ,Sardasht,Arak

City
Arak

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Markazi

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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

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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
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Person responsible for updating data

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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