Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Comparison between Intravenous Xylocaine, Mg sulfate and Amiodarone in the Prevention of Cardiac Arrhythmias after Aortic Declamping in Coronary Artery Bypass Surgery

Protocol summary

Summary

Objective: To compare the effects of lidocaine, Amiodarone intravenous magnesium sulfate in preventing ventricular arrhythmia after aortic cross-declamping of in coronary artery bypass surgery. Study design: randomized, single-blind clinical trial. Inclusion criteria: patients undergoing elective surgery for coronary artery bypass surgery. Exclusion criteria: history of using antiarrhythmic drugs; heart block (RBBB-LBBB-LAHB-LPHB) or pacemakers. Two hundred patients undergoing elective surgery for coronary artery bypass surgery divided into four groups: the first group received placebo, second group received 1.5 mg / kg lidocaine, third group received 2 mg of magnesium sulfate and group IV received Amiodarone 150 mg intravenous immediately before aortic cross declamping. The incidence of arrhythmias is observed in this period among the four groups. Until completely disconnecting the patient from the pump other measures to treat arrhythmias such shocks should be recorded. Drugs and placebo will be injected by third person when patient is rewarming (warm the patient up to 37 °) exactly 5 minutes before aortic cross-declamping. Arrhythmia in aortic cross-declamping, drugs, inotropes, shock, balloon pumps will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017040519470N55**
Registration date: **2017-06-22, 1396/04/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-22, 1396/04/01

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research,Gerash University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between Intravenous Xylocaine, Mg sulfate and Amiodarone in the Prevention of Cardiac Arrhythmias after Aortic Declamping in Coronary Artery Bypass Surgery

Public title

Comparison between Intravenous Xylocaine, Mg sulfate and Amiodarone in the Prevention of Cardiac Arrhythmias after Aortic Declamping in Coronary Artery

Bypass Surgery

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: patients undergoing elective surgery for coronary artery bypass surgery. Exclusion criteria: history of using antiarrhythmic drugs; heart block (RBBB-LBBB-LAHB-LPHB) or pacemakers.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
block randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Gerash University of Medical Sciences

Street address
Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City
Gerash

Postal code

Approval date
2015-09-23, 1394/07/01

Ethics committee reference number
IR.GERUMS.REC.1395.1.16

Health conditions studied

1

Description of health condition studied
Coronary Artery Bypass Surgery

ICD-10 code
I25.1

ICD-10 code description
Atherosclerotic heart disease

Primary outcomes

1

Description
arrhythmias

Timepoint
after aortic cross declamping perioperatively

Method of measurement
EKG monitoring

2

Description
Total inotropes consumption

Timepoint
Perioperatively

Method of measurement
Observasion

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: patients received 1.5 mg / kg lidocaine, intravenous immediately before declamping.

Category
Treatment - Drugs

2

Description
Intervention group 2: patients received 2 mg of magnesium sulfate intravenous immediately before declamping.

Category
Treatment - Drugs

3

Description
Intervention group 3: patients received 150 mg Amiodarone intravenous immediately before declamping.

Category
Treatment - Drugs

4

Description
Control group: patients received 5 CC normal saline immediately before declamping.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahi Faghihi Hospital
Full name of responsible person
Jalal Saeem
Street address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research, Shiraz University of Medical Sciences
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Vice chancellor of research ,Emam Hosein boulevard , Danshjoo street Gerash University of Medical Sciences
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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
Vice Chancellor for Research, Shiraz University of Medical Sciences

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

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Person responsible for updating data

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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