

# 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

2017-06-22, 1396/04/01

#### 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

#### Registrant information

##### Name

Farzaneh Masihi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3647 4270

##### Email address

masihif@sums.ac.ir

#### 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**

Observation

## **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**

Shahid Faghihi Hospital, Zand Street

**City**

Shiraz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice Chancellor for Research, Shiraz University of Medical Sciences

**Full name of responsible person**

Dr Jalal Saeem

**Street address**

Vice chancellor of research ,Emam Hosein boulevard ,  
Danshjoo street Gerash University of Medical Sciences

**City**

Gerash

**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

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Elahe Allahyari

**Position**

Fellow ship of cardioanesthesiology

**Other areas of specialty/work**

**Street address**

Anesthesiology Department, Faghihi Hospital, Zand

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## Person responsible for scientific inquiries

### Contact

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Cardio-anesthesiologist

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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**Position**

MS in english teaching ,BS in anesthesia/English Consultant

**Other areas of specialty/work**

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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*