

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of using Lidocaine versus Amiodarone for the prevention of Tachy ventricular arrhythmias after removal of Aorta cross clamp during valvular heart surgery

Protocol summary

Study aim

Comparison of Amiodarone and Lidocaine use in preventing the occurrence of ventricular tachyarrhythmias after aortic clamp removal during cardiac valve surgery

Design

Sample size: In this study, 60 patients will be randomly divided into two groups of 30 patients. Randomization will be done using blocks of size 4. This study is a single-blind clinical trial with parallel groups.

Settings and conduct

Patients Candidate for Cardiac Valve Surgery at Shahid Rajaei Pharmacy Center will receive Antiarrhythmic Drugs in Two Groups During Bypass and 5 Minutes Before Cross Clamp Opening.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient satisfaction to participate in the study; Patients candidate for open heart valve surgery; Patients over 18 years of age; normal liver enzyme levels; serum creatinine levels less than 2 mg/dl. Non-inclusion criteria: Ejection fraction less than 30%; Carotid artery stenosis greater than 50%; previous cardiac surgery; Contraindication or severe hypersensitivity to amiodarone; lidocaine and magnesium sulfate.

Intervention groups

Intervention group 1: Lidocaine plus Magnesium Sulfate; Lidocaine 2 mg / kg plus Magnesium Sulfate 30 mg/kg and normal saline will be administered up to a total volume of 25 ml using infusion pump 5 minutes before the cross-clamp is opened. Intervention group 2: 300 mg Amiodarone plus Magnesium Sulfate 30 mg/kg and normal saline up to a total volume of 25 ml will be administered by infusion pump 5 minutes before the cross-clamp is opened.

Main outcome variables

Occurrence ventricular tachyarrhythmias

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190901044663N1**

Registration date: **2020-07-08, 1399/04/18**

Registration timing: **retrospective**

Last update: **2020-07-08, 1399/04/18**

Update count: **0**

Registration date

2020-07-08, 1399/04/18

Registrant information

Name

Fateme Hesari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3678 1654

Email address

hessari.fateme@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-21, 1398/05/30

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

2019-08-21, 1398/05/30

Actual recruitment end date

2019-11-11, 1398/08/20

Trial completion date

2019-11-11, 1398/08/20

Scientific title

Comparison of using Lidocaine versus Amiodarone for the prevention of Tachy ventricular arrhythmias after removal of Aorta cross clamp during valvular heart surgery

Public title

Comparison of using Lidocaine versus Amiodarone for the prevention of tachy ventricular arrhythmias

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patient consent to participate in the study 18 years of age or older No previous cardiac surgery No contraindication or severe allergy to amiodarone, Lidocaine and Magnesium Sulfate Normal serum levels of liver enzymes Serum creatinine levels are less than 2 mg / dL.

Exclusion criteria:

Transient cerebral ischemia or stroke Uncontrolled diabetes mellitus during study Carotid artery stenosis over 50% Uncontrolled hypertension

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a block randomization method is used. Randomization unit is individual and the tool used to randomize is the closed envelope. Inside each envelope is the English letter A or B. Patients fall into the Amiodaron or Lidocaine group according to the word that came out of the envelop.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participant is unaware of the prescribed medication due to general anesthesia, and the data analyst, safety committee, and data monitor also do not have access to the checklist.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shaheed Rajaie Cardiovascular Medical and Research Center

Street address

Beside Mellat park; Niayesh Intersection; Valiasr street; Tehran

City

Tehran

Province

Tehran

Postal code

1995614331

Approval date

2019-11-17, 1398/08/26

Ethics committee reference number

IR.RHC.REC.1398.37

Health conditions studied

1

Description of health condition studied

Ventricular tachycardia

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Ventricular tachycardia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Occurrence of ventricular tachyarrhythmias

Timepoint

During the bypass and 5 minutes before the cross-clamp opening

Method of measurement

Electrocardiograph

Secondary outcomes

1

Description

Ejection Fraction

Timepoint

24 hours after intervention

Method of measurement

Echocardiography

Intervention groups

1

Description

Intervention group 1: Lidocaine plus Magnesium Sulfate; Lidocaine 2 mg / kg plus Magnesium Sulfate 30 mg/kg and normal saline will be administered up to a total volume of 25 ml using infusion pump 5 minutes before the cross-clamp is opened.

Category

Prevention

2

Description

Intervention group 2: 300 mg Amiodarone plus Magnesium Sulfate 30 mg/kg and normal saline up to a total volume of 25 ml will be administered by infusion pump 5 minutes before the cross-clamp is opened.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

Fateme Hesari

Street address

No. 19, Sadat alley, Rajaie street, Shahid Ardestani town

City

Pishva

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123456789021

Phone

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

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Grant name

0

Grant code / Reference number

0

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Rajaie Cardiovascular Medical and Research Center

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

Shahid Rajaee Cardiovascular Medical and Research Center

Full name of responsible person

Fateme Hesari

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Others

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

Fateme Hesari

Position

Student Master

Latest degree

Bachelor

Other areas of specialty/work

Others

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Person responsible for updating data

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Position

Master Student

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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