Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effect of lidocaine- magnesium sulfate with amiodarone- magnesium sulfate in preventing ventricular fibrillation after aortic cross clamp removal in coronary artery graft surgery

Protocol summary

Summary

The purpose of this study is the comparing the effect of lidocaine - magnesium sulfate with Amiodarone - Magnesium sulfate in preventing ventricular fibrillation after aortic cross clamp removal in coronary artery graft surgery Design: A prospective double blinded block randomized study Inclusion criteria: coronary artery atherosclerosis, ASA class 3-4, negative history of cardiopulmonary resuscitation, patients with a no history of intake drugs (digoxin, amiodarone, lidocaine, magnesium). Exclusion criteria: contraindication for drug intake or allergy to drugs, history of previous cardiac surgery, emergency surgery. Method: Midazolam, fentanyl, etomidate and cis-atracurium were applied for induction of anesthesia. Continuous infusion of sufentanil, midazolam and atracurium were applied for anesthesia maintenance. All patients received a 10 minutes infusion of magnesium sulfate (30mg/kg) before releasing the aortic cross clamp. Group A: A1 syringe pump (normal saline) and A2 syringe pump (100 mg lidocaine) are applied. Group B: B1 syringe pump (amiodarone 300 mg) and B2 syringe pump (normal saline) are applied. Syringes no. 1 and 2 in equal volumes of 10 cc which are applied 10 and 2 minutes before clamp removal respectively. Outcome measurements: Demographic values, ejection fraction, valvular indices, type of arrhythmia, defibrillation, drug therapy, central venous and mean arterial pressures, heart rate, blood gas indices, plasma concentrations (sodium, potassium, glucose and hematocrite), duration of cardiopulmonary pump, temperature at clamp release time, hemofilterate and cardioplegic volume.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015081723660N1**
Registration date: **2017-01-20, 1395/11/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-01-20, 1395/11/01

Registrant information

Name

Maryam moradi shahdadi

Name of organization / entity

Hormozgan university of mediical sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Hormozgan University of Medical Sciences

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of lidocaine- magnesium sulfate

with amiodarone-magnesium sulfate in preventing ventricular fibrillation after aortic cross clamp removal in coronary artery graft surgery

Public title
Comparing the effect of lidocaine and magnesium sulfate combination with amiodarone and magnesium sulfate combination in preventing ventricular fibrillation heart rhythms after aortic artery occlusion clamp removal during the coronary artery graft surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: ASA class 3-4, atherosclerosis vessel coronary-history with no previous cardiopulmonary resuscitation, patients with no medication of digoxin-amiodarone-lidocaine-magnesium Exclusion criteria: Concurrent other cardiac surgery, emergency surgery, allergy to drugs
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Deputy for Research, and Medical Ethics Committee of Hormozgan University of Medical Sciences
Street address
Joomhoori Islami Blv., Shahid Mohammadi Hospital
City
Bandar Abbas
Postal code
7919915519
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
HUMS-REC-1394-65

Health conditions studied

1

Description of health condition studied
Ventricular fibrillation in coronary artery bypass graft operation
ICD-10 code
I49.0
ICD-10 code description
Ventricular fibrillation and flutter

Primary outcomes

1

Description
Ventricular fibrillation
Timepoint
15 minute before operation till 24 hours after operation in ICU
Method of measurement
Electrocardiography

Secondary outcomes

1

Description
Central venous pressure
Timepoint
15 minutes after anesthesia induction and 15 minutes after starting cardiopulmonary bypass
Method of measurement
Central venous pressure transducer monitor

2

Description
Mean arterial pressure
Timepoint
15 minutes after anesthesia induction and 15 minutes after starting cardiopulmonary bypass
Method of measurement
Invasive arterial blood pressure monitor

3

Description
heart rate
Timepoint
15 minutes after anesthesia induction and 15 minutes after starting cardiopulmonary bypass
Method of measurement
electrocardiography monitor

4

Description
Arterial blood gases (pH, arterial partial pressure of

oxygen, arterial partial pressure of carbon dioxide, bicarbonate concentration)

Timepoint

At phases of (base line, heart arrest, patient warming, and pump separation)

Method of measurement

Arterial catheter blood sampling

5

Description

Plasma (Na-K) electrolytes

Timepoint

At phases of (base line, heart arrest, patient warming, and pump separation)

Method of measurement

Arterial catheter blood sampling

6

Description

Blood plasma glucose

Timepoint

At phases of (base line, heart arrest, patient warming, and pump separation)

Method of measurement

Arterial catheter blood sampling

7

Description

Complete blood count of plasma

Timepoint

At phases of (base line, heart arrest, patient warming, and pump separation)

Method of measurement

Arterial catheter blood sampling

Intervention groups

1

Description

All the patients received a standard monitoring, arterial and central venous catheter insertion. Premedication was applied by administering midazolam (0.05 mg/kg) with fentanyl (10 microgram/kg) and for anesthesia induction, etomidate (0.2 mg/kg), cis-atracurium (0.2 mg/kg) were administered, tracheal intubation and mechanical ventilation was established thereafter. Anesthesia was maintained by the infusion of sufentanil (0.01 microgram/kg/min), midazolam (1 mg/kg/min) and atracurium (8 microgram/kg/min). All the patients received a 30 mg/kg of sulphate magnesium through the bypass pump 10 minutes before the aortic cross clamp removal. The events recordings during anesthesia and drug administrations were performed by a qualified anesthesia technician who was not aware of the contents of the study syringes. Group A: Received the syringe pump A1 (10 cc of normal saline) 10 minutes before the opening of the aortic cross clamp and syringe pump A2 (2% lidocaine 1.5 mg/kg) 2 minutes before opening the aortic cross clamp were administered to the patients.

Category

Treatment - Drugs

2

Description

All the patients received a standard monitoring, arterial and central venous catheter insertion. Premedication was applied by administering midazolam (0.05 mg/kg) with fentanyl (10 microgram/kg) and for anesthesia induction, etomidate (0.2 mg/kg), cis-atracurium (0.2 mg/kg) were administered, tracheal intubation and mechanical ventilation was established thereafter. Anesthesia was maintained by the infusion of sufentanil (0.01 microgram/kg/min), midazolam (1 mg/kg/min) and atracurium (8 microgram/kg/min). All the patients received a 30 mg/kg of sulphate magnesium through the bypass pump 10 minutes before the aortic cross clamp removal. The events recordings during anesthesia and drug administrations were performed by a qualified anesthesia technician who was not aware of the contents of the study syringes. Group B: Received the syringe pump B1 (10 cc solution of 300 mg amiodarone and normal saline) 10 minutes before the opening of the aortic cross clamp and syringe pump B2 (5 cc of normal saline) 2 minutes before opening the aortic cross clamp were administered to the patients.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohammadi Hospital

Full name of responsible person

Saeid Kashani

Street address

Joomhoori Islami Blv., Shahid Mohammadi Hospital

City

Bandar Abbas

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hormozgan University of Medical Sciences

Full name of responsible person

Abdulazim Nejatizadeh

Street address

Joomhoori Islami Blv., Deputy of Research Center, Shahid Mohammadi Hospital

City

Bandar Abbas

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hormozgan 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

Hormozgan University of Medical Sciences

Full name of responsible person

Saeid Kashani

Position

Assistant Professor of Anesthesiology and Intensive care, Fellowship of Cardiac Surgery Anesthesia

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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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