Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

comparison the effectiveness of dexmedetomidine with midazolam on incidence of cardiac arrhythmia in off-pump coronary artery bypass surgery patients, a clinical trial.

Protocol summary

Summary

Objective: To comparison the effectiveness of dexmedetomidine with midazolam on incidence of cardiac arrhythmia in off-pump coronary artery bypass surgery patients. Design: A single blind block randomized clinical trial. Study population: Patients will be undergoing off-pump coronary artery bypass surgery. Inclusion criteria: Patients undergoing off-pump coronary artery bypass surgery; sustaining ASA I and ASA II; aged between 18-75 years; EF more than 35%. Exclusion criteria: History of arrhythmias or heart block; EF less than 35%; history of cardiac surgery; history of valvular heart disease; having left atrial enlargement (LAE) or cardiomegaly. Sample size: 70 cases. Study intervention: Control group is receiving 0.5 mg/kg midazolam addition of 10 mcg/kg fentanyl, 0.5 mg/kg atracurium, and 1.5 mg/kg propofol for induction of anesthesia. Interventional group is receiving 1 mcg/kg dexmedetomidine infusion for induction of anesthesia for 10 minutes, and then infusion is fallowing up with 0.2 to 0.6 mg/kg/h based on tolerance of patient for MAP decreased in ICU after surgery until 24 hours. Study outcome: Evaluation and comparison of cardiac arrhythmia rate, hemodynamic changes, the urge to use anesthetic drugs, heart block, myocardial infarction, and cardiac arrest with heart monitoring in control and interventional groups during and after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072413159N9**
Registration date: **2016-07-30, 1395/05/09**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-07-30, 1395/05/09

Registrant information

Name
Shima Sheybani
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Mashhad University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison the effectiveness of dexmedetomidine with midazolam on incidence of cardiac arrhythmia in off-pump coronary artery bypass surgery patients, a clinical trial.

Public title

The incidence of cardiac arrhythmia in coronary artery

bypass surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients undergoing off-pump coronary artery bypass surgery; sustaining ASA I and ASA II; aged between 18-75 years; EF more than 35%. Exclusion criteria: History of arrhythmias or heart block; EF less than 35%; history of cardiac surgery; history of valvular heart disease; having left atrial enlargement (LAE) or cardiomegaly.

Age

From **30 years** old to **85 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Postal code

Approval date

2015-06-13, 1394/03/23

Ethics committee reference number

IR.MUMS.fm.REC.1394.704

Health conditions studied

1

Description of health condition studied

Cardiopulmonary bypass

ICD-10 code

I27.9

ICD-10 code description

Pulmonary heart disease, unspecified

Primary outcomes

1

Description

Cardiac arrhythmia rate

Timepoint

During and 24 hours after surgery

Method of measurement

Heart monitoring

Secondary outcomes

1

Description

Hemodynamic changes

Timepoint

During and 24 hours after surgery

Method of measurement

Heart monitoring

Intervention groups

1

Description

Control group: Patients are receiving 0.5 mg/kg midazolam addition of 10 mcg/kg fentanyl, 0.5 mg/kg atracurium, and 1.5 mg/kg propofol for induction of anesthesia. Cardiac arrhythmia rate and hemodynamic changes are measurement with heart monitoring during and after surgery.

Category

Treatment - Drugs

2

Description

Interventional group: Patients are receiving 1 mcg/kg dexmedetomidine infusion for induction of anesthesia for 10 minutes, and then infusion is fallowing up with 0.2 to 0.6 mg/kg/h based on tolerance of patient for MAP decreased in ICU after surgery until 24 hours. Cardiac arrhythmia rate and hemodynamic changes are measurement with heart monitoring during and after surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Shima Sheybani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
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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, Mashhad 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
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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