

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 following 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

Country

Iran (Islamic Republic of)

Phone

+98 51 3764 7230

Email address

sheybanish@mums.ac.ir

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 following 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

Street address

Ghaem Hospital, Ahmadabad Avenue

City

Mashhad

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

Street address

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

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Mashhad

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

Mashhad University of Medical Sciences

Full name of responsible person

Shima Sheybani

Position

Anesthesiologist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Seyed Saeed Jahanbakhsh

Position

Cardiothoracic Anesthesiology Fellowship

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Shima Sheybani

Position

Anesthesiologist

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