

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The Impact of Postoperative Dexmedetomidine on Outcomes of Orally Addicted Patients Undergoing Off Pump Coronary Artery Bypass Grafting

Protocol summary

Study aim

Today, there are many drugs to reduce pain in opiate and non-opioid groups, and dexmedetomidine is one of the drugs that has both analgesic and sedative effects. On the other hand, studies have shown that the use of this drug can reduce the incidence of delirium, acute kidney damage, arrhythmias and the need for opiate in cardiac surgery. Since the incidence of each of these complications increases costs, hospitalization length and hospitalization and morbidity and mortality after cardiac surgery, we found that the effect of this drug on the outcomes of patients undergoing cardiac surgery.

Design

This randomized, double-blind study will be performed on 120 patients undergoing cardiac surgery. All adult patients with cardiac surgery undergoing off pump surgery, and those patients are affiliated with oral opioids. Enter the study All Emergency / surgery with Pumps / and EF Under 30% / Addiction to iv opioids / This study will be conducted in the Department of Cardiac Surgery, Imam Reza Hospital, Mashhad, in 2017-2018 years. Expected outcomes 1. Reducing postoperative pain in open heart surgery patients 2. Reducing the number of ventilator days needed in open heart surgery patients 3. Reducing postoperative delirium in open heart surgery patients 4. Reducing the duration of mechanical ventilation in cardiac surgery patients 5. Reduced hospitalization time in ICU in open heart surgery patients 6. Reduced hospitalization time in open heart surgery patients 7. Reduced need for opioids in open heart surgery patients 8. Reduced prevalence and acute renal damage in patients with open heart surgery

Settings and conduct

This study was conducted blindly and based on random numbers of numbers in the Imam Reza Department of Surgery in the form of a random triple.

Participants/Inclusion and exclusion criteria

All adult patients with cardiac surgery undergoing off pump surgery, and those patients are affiliated with oral

opioids. Enter the study All Emergency / surgery with Pumps / and EF Under 30% / Addiction to iv opioids

Intervention groups

The aim of this study was to evaluate the effect of dexmedetomidine with placebo in two groups and its effects on pain, renal failure, arrhythmia, delirium, and mechanical ventilation.

Main outcome variables

Expected outcomes 1. Reducing postoperative pain in open heart surgery patients 2. Reducing the number of ventilator days needed in open heart surgery patients 3. Reducing postoperative delirium in open heart surgery patients 4. Reducing the duration of mechanical ventilation in cardiac surgery patients 5. Reduced hospitalization time in ICU in open heart surgery patients 6. Reduced hospitalization time in open heart surgery patients 7. Reduced need for opioids in open heart surgery patients 8. Reduced prevalence and acute renal damage in patients with open heart surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150216021098N4**

Registration date: **2018-03-10, 1396/12/19**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-10, 1396/12/19**

Update count: **0**

Registration date

2018-03-10, 1396/12/19

Registrant information

Name

Shahram Amini

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)	Participants, Care Provider, Outcome Assessor, and the Data Analyzer are Blind to the Study.
Phone +98 51 3852 5209	Placebo Used
Email address aminish@mums.ac.ir	Assignment Parallel
Recruitment status Recruitment complete Funding source	Other design features
Expected recruitment start date 2017-08-23, 1396/06/01	Secondary Ids empty
Expected recruitment end date 2018-07-23, 1397/05/01	Ethics committees
Actual recruitment start date empty	<u>1</u>
Actual recruitment end date empty	Ethics committee
Trial completion date empty	Name of ethics committee Ethics committee of Mashhad University of Medical Sciences
Scientific title The Impact of Postoperative Dexmedetomidine on Outcomes of Orally Addicted Patients Undergoing Off Pump Coronary Artery Bypass Grafting	Street address Mashhad University of Medical Sciences.daneshgah Ave;ghoreshi departeman
Public title The Impact of Dexmedetomidine on Patients Undergoing Coronary Artery Bypass Grafting	City Mashhad
Purpose Prevention	Province Razavi Khorasan
Inclusion/Exclusion criteria Inclusion criteria: Adult patients with oral opium abuse undergoing elective off pump coronary artery bypass grafting Exclusion criteria: Use of Cardiopulmonary Pump Life threatening Arrhythmias Massive intraoperative Bleeding Requiring More Than 1 Unit of Packed RBC Use of Intraaortic Balloon Pump Need for High Dose Vasopressors Decline of Consent Sensitivity to Dexmedetomidine Ejection Fraction Less Than 30%	Postal code 13944-91388
Age From 18 years old	Approval date 2017-07-23, 1396/05/01
Gender Both	Ethics committee reference number IR.MUMS.fm.1396.143
Phase N/A	Health conditions studied
Groups that have been masked - Participant - Outcome assessor - Data analyser	<u>1</u> Description of health condition studied Coronary Artery By[pass Grafting ICD-10 code I25.7 ICD-10 code description Atherosclerosis of coronary artery bypass graft(s) and coronary artery of transplanted heart with angina pectoris
Sample size Target sample size: 120	<u>2</u> Description of health condition studied Opium Abuse ICD-10 code Z71.51 ICD-10 code description Drug abuse counseling and surveillance of drug abuser
Randomization (investigator's opinion) Randomized	Primary outcomes
Randomization description Use of Computerized Randomization Table	<u>1</u>
Blinding (investigator's opinion) Double blinded	Description Pain Severity
Blinding description	

Timepoint

Every 1 hour

Method of measurement

NSR-CPOT

2**Description**

Frequency of delirium

Timepoint

Every 8 hour

Method of measurement

ICAM

3**Description**

Duration of Mechanical Ventilation

Timepoint

Every 1 hour

Method of measurement

Cornometer

4**Description**

Need for Additional Opiates

Timepoint

Every 1 hour

Method of measurement

Dose Drug

Secondary outcomes**1****Description**

Renal Failure

Timepoint

Daily until admitted

Method of measurement

Cratinin/ out put

Intervention groups**1****Description**

Patients randomly divided into two groups according to the random numbers table. In the case group, the dexmedetomidine is administered at 1 µg / kg body weight in 15 minutes and then 0.2 µg / kg body weight per hour for 24 hours. In the placebo group, normal saline is infused. The variables will then be recorded

Category

Treatment - Drugs

2**Description**

Control group: In the control group, normal saline is infused at the same rate for 24 hours and the variables

will be recorded.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Reza hospital-ICU OH

Full name of responsible person

Akram Asadpour

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Web page address<http://www.mums.ac.ir/newmums/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Web page address<http://v-research.mums.ac.ir/>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad University of Medical Sciences

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

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Mashhad University of Medical Sciences

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Position

Professor

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Other areas of specialty/work

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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