Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 dexmedmodine 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 studyAll 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 randum 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 studyAll 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 dexmedtomedine with placebo in two groups and its effects on pain, renal failure, arythemia, 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)

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aminish@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

The Impact of Dexmedetomidine on Patients Undergoing Coronary Artery Bypass Grafting

Purpose

Prevention

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 Bleding Requring 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%

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Use of Computerized Randomization Table

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, Care Provider, Outcome Assessor, and the Data Analyzer are Blind to the Study.

Placebo

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

Mashhad University of Medical Sciences.daneshgah Ave;ghoreshi departeman

City

Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Approval date

2017-07-23, 1396/05/01

Ethics committee reference number

IR.MUMS.fm.1396.143

Health conditions studied

1

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

2

Description of health condition studied

Opium Abuse

ICD-10 code

Z71.51

ICD-10 code description

Drug abuse counseling and surveillance of drug abuser

Primary outcomes

1

Description

Pain Severity

Timepoint
Every 1 hour
Method of measurement
NSR-CPOT

2

Description
Frequence of delireum
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 Failur
Timepoint
Daily until admitted
Method of measurement
Cratenin/ out put

Intervention groups

1

Description
Patients randomly divided into two groups according to the random numbers table. In the case group, the dexmedtomdin 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi (Pharm.D., Ph.D.)
Street address
GHoreyshi building, Daneshgah street, Mashhad, Iran
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tafaghodim@mums.ac.ir
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

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Shahram Amini
Position
Professor
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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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