Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison effect of Morphine and dexmedtomidine infusion on intubation time and hemodynamic parameters in patients undergone coronary artery bypass surgery who admitted in Intensive Care Unit

Protocol summary

Study aim
Determination and comparison of the effect of dexmedetomidine and morphine infusion on duration of mechanical ventilation and hemodynamic parameters in patients undergoing coronary artery bypass graft surgery

Design
This is a double blind, randomized control, phase 3, clinical trial study with parallel groups. 70 patients undergoing coronary artery bypass graft surgery were randomly assigned into two groups of 35 intervention and control groups.

Settings and conduct
This study was carried out in 2020 at Alzahra Hospital in Isfahan. In this double blind study, patients and researcher were unaware of the type of drug being administered.

Participants/Inclusion and exclusion criteria
Inclusion criteria: over 18 years old, candidate for coronary artery bypass surgery, patient consent to participate in the study. Exclusion criteria: Addiction, Use psychotropic and antidepressant drugs, use drugs Affecting on Hemodynamics and aus Anti-coagulant drugs

Intervention groups
Intervention group: Receive Dexmedetomidine plus morphine Control group: Receive Morphine plus normal saline

Main outcome variables
Duration of mechanical ventilation, Blood pressure, Heart rate, Blood oxygen saturation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130311012782N39**
Registration date: **2020-02-22, 1398/12/03**
Registration timing: **prospective**

Last update: **2020-02-22, 1398/12/03**
Update count: **0**

Registration date
2020-02-22, 1398/12/03

Registrant information

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Name of organization / entity
Isfahan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-02, 1399/01/14

Expected recruitment end date
2020-10-20, 1399/07/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison effect of Morphine and dexmedtomidine infusion on intubation time and hemodynamic parameters in patients undergone coronary artery

bypass surgery who admitted in Intensive Care Unit

Public title
Comparison of the effect of adding dexmedetomidine to morphine on duration of mechanical ventilation and heart rate and hypertension in open heart surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patient undergoing coronary bypass surgery Heart ejection friction below 40% Patient's consent to participate in the study
Exclusion criteria:
Addiction Use of psychotropic and antidepressant drugs Use of Effective drugs on hemodynamic status Use of anticoagulant drugs
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 70 patients with inclusion criteria were divided into two groups of 35 using Random Allocation Software. At first the total sample size is entered into the software and in the next section the number of study groups is entered. Output of Software includes a list that distributes participants from 1 to 70 randomly into two groups. Patients are divided into two groups according to the time of referral in order to reach the required sample size in each group.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is a double blind study and patients and researchers are unaware of the type of drug being administered. The drugs are provided by a staff member of the operating room who is not in the study on similar, coded syringes and provided to the project administrator for injection.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Deputy of Research and Technology, Isfahan University of Medical Sciences, Hezar Jerib street
City
Isfahan
Province
Isfehan
Postal code
8434193474
Approval date
2015-11-21, 1394/08/30
Ethics committee reference number
IR.MUI.MED.REC.1398.016

Health conditions studied

1

Description of health condition studied
Coronary Artery Bypass Graft Surgery
ICD-10 code
125.810
ICD-10 code description
Atherosclerosis of coronary artery bypass graft(s) without angina pectoris

Primary outcomes

1

Description
Duration of mechanical ventilation
Timepoint
In the end of surgery
Method of measurement
Mechanical ventilation machine

2

Description
Blood Pressure
Timepoint
Every 15 minutes during operation and recovery
Method of measurement
Pulse Oximeter

3

Description
Heart Rate
Timepoint
Every 15 minutes during operation and recovery
Method of measurement
Pulse Oximeter

4

Description
percent of Blood Oxygen Saturation
Timepoint
Every 15 minutes during operation and recovery
Method of measurement
Pulse Oximeter

Secondary outcomes

1

Description
postoperative complications
Timepoint
Duration of recovery
Method of measurement
Physical examination

Intervention groups

1

Description
Intervention group: Dexmedetomidine recipient 0.25 µg / kg / hour, plus morphine 0.25 mg / kg/ hour in 50 ml volume upon admission to intensive care unit.
Category
Prevention

2

Description
Control group: Morphine recipient 0.25 µg / kg / hour, plus normal saline in 50 ml volume upon admission to intensive care unit.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Chamran hospital
Full name of responsible person
Gholamreza Masoumi
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Sponsors / Funding sources

1

Sponsor
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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
Esfahan 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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
The project is owned by the state agency and cannot be published.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available