

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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

Name

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3629 1510

Email address

mehrabi@mui.ac.ir

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 fraction 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

Isfahan

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

Street address

Shahid Chamran hospital, Moshtagh 3 street

City

Isfahan

Province

Isfahan

Postal code

8434193474

Phone

+98 31 3669 2174

Email

gh_masoumi@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Deputy of research and technology, Isfahan University of Medical Sciences, Heza Jeib street

City

Isfahan

Province

Isfahan

Postal code

8434193474

Phone

+98 31 3792 3070

Email

sh_haghjoo@med.mui.ac.ir

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

Esfahan University of Medical Sciences

Full name of responsible person

Amirreza Hemasian

Position

Resident of anesthesiology

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Shahid Chamran hospital, Moshtagh 3 street

City

Isfahan

Province

Isfahan

Postal code

8434193474

Phone

+98 31 3668 5555

Email

amirreza.hemasian@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Mojtaba Mansouri

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Shahid Chamran hospital, Moshtagh 3 street

City

Isfahan

Province

Isfahan

Postal code

8434193474

Phone

+98 31 3669 2174

Email

m_mansouri@med.mui.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Ali Mehrabi

Position

Statistical Consultant

Latest degree

Master

Other areas of specialty/work

Epidemiology

Street address

Deputy of research, school of medicine, Isfahan University of Medical Sciences, Hezar Jerib street

City

Isfahan

Province

Isfahan

Postal code

8434193474

Phone

+98 31 3792 8081

Email

al.mehrabi@gmail.com

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