

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

A Comparison between the effects of Dexmedetomidine and Morphine used by patient-controlled anesthesia pump Method on controlling the side effects of Post-operative coronary bypass surgery in intensive care unit at Bushehr heart center in 1394 to 1395

Protocol summary

Summary

Objective of the study: To compare the effects of two analgesics, Dexmedetomidine and Morphine used by patient-controlled anesthesia pump on the side effects of post operative coronary bypass surgery in Intensive Care Unit of Bushehr heart center in 2016 to 2017. This is a randomized, single-blinded trial containing interventional and control groups. Methodology: The population is composed of 80 patients between the ages of 40 to 80 years who will be grouped into two groups of A and B. Inclusion criteria: Ejection fraction percentage less than 35 %; Patients with informed refusal after the explanation of the procedures; Patients who need reoperation in the first 24 hours after the surgery; Drug Addiction. Intervention: after randomization, Patients in group A(interventional group) will be subjected to patient-controlled Anesthesia pump containing 100 cc Normal Saline + 200 micro gram Dexmedetomidine + 4 mili gram Ondansetron with the rate of 0.7 micro gram per kilo gram per hour and group B (control) patients will be subjected to patient-controlled Anesthesia pump containing 10 miligram Morphine + 4miligram Ondansetron with the rate of 0.015 miligram per kilo gram per hour. This study will be performed from 03/04/2016 to 19/03/2017. Outcomes which will be measured and compared in this study between the groups are: severity of the pain, changes of Hemodynamic parameters, the amount of required Narcotic analgesias, the frequency of nausea and vomiting and also the level of sedation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042427565N1**

Registration date: **2017-04-10, 1396/01/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-10, 1396/01/21

Registrant information

Name

Hosein Ashkpoor Motlagh

Name of organization / entity

Bushehr University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 77 3332 3846

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h.ashkpoor@bpums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Bushehr University of Medical Sciences

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2017-05-05, 1396/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison between the effects of Dexmedetomidine and Morphine used by patient-controlled anesthesia pump Method on controlling the side effects of Post-operative coronary bypass surgery in intensive care unit at Bushehr heart center in 1394 to 1395

Public title

Comparing Dexmedetomidine and Morphine used Patient-Controlled Analgesia pump Method on controlling the side effects of Cardiac Surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Patients undergoing elective coronary artery bypass graft surgery. Exclusion criteria: Ejection fraction percentage less than 35 %; patients who need reoperation in the first 24 hours after the surgery; Drug Addiction; Patients with informed refusal after the explanation of the procedures.

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

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 Bushehr university of medical science

Street address

Post code: 7514633341, Next to Tamin Ejtemaea Organisation, After Dadgostari Crossroads, Imam Qomeyni street, Bushehr

City

Bushehr

Postal code

7514633341

Approval date

2016-04-03, 1395/01/15

Ethics committee reference number

IR.BPUMS.rec.13940107

Health conditions studied

1

Description of health condition studied

general anesthesia

ICD-10 code

Y48.4

ICD-10 code description

Anaesthetic, unspecified

2

Description of health condition studied

cardiac surgery

ICD-10 code

T81.9

ICD-10 code description

Unspecified complication of procedure

Primary outcomes

1

Description

The intensity of analgesia

Timepoint

First 24 hours after surgery

Method of measurement

Visual analogue scale

2

Description

Systolic blood pressure

Timepoint

First 24 hours after surgery

Method of measurement

In millimeters of mercury using mercury manometer

3

Description

Diastolic blood pressure

Timepoint

First 24 hours after surgery

Method of measurement

In millimeters of mercury using mercury manometer

4

Description

Mean arterial pressure

Timepoint

First 24 hours after surgery

Method of measurement

(twice systolic blood pressure+diastolic blood pressure in millimeters of mercury and by mercury barometer)

Divided by 2

Secondary outcomes

1

Description

Sedation level

Timepoint

First 24 hours after surgery

Method of measurement

By Ramsay sedation scale

2

Description

Heart rate

Timepoint

First 24 hours after surgery

Method of measurement

Measuring the radial pulse by palpation in one minute

3

Description

Nausea and Vomiting

Timepoint

First 24 hours after surgery

Method of measurement

Patient's self complaining

Intervention groups

1

Description

Intervention group: Dexmedetomidine 200 micro gram in 100 cc Normal Saline plus 4 mg Ondansetron in Patient-Controlled Anesthesia pump with infusion rate of 0.7 micro gram per kilogram per hour in the first 24 hours after the surgery

Category

Treatment - Drugs

2

Description

Control group: Morphine 10 milligram with 4 mg Ondansetron into pump with infusion rate of 0.015 micro gram per kilogram per hour in the first 24 hours after the surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Heart hospital of Bushehr university of medical science

Full name of responsible person

DR AbdolRasool Anvaripoor

Street address

Postcode 7514633341, Heart hospital of Bushehr University of Medical science, Next to Tamin Ejtemaei Department, After Dadgostari Crossroads, Moalem street, Bushehr

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Bushehr University of Medical Sciences

Full name of responsible person

Mrs. Fatemeh Besharat Zadeگان

Street address

Postcode 7514633341, Pardis Department of Bushehr university of Medical science, Rishahr Street, Bushehr

City

Bushehr

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, Bushehr 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

Bushehr Central Heart Department

Full name of responsible person

Doctor Abdol Rasool Anvaripoor

Position

Anesthesiologist

Other areas of specialty/work

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Postcode 7514633341, Bushehr Heart Medical and Educational center, After Dadgostari Crossroad, Moalem Street, Bushehr

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Bushehr Heart Medical and Educational center

Full name of responsible person

Doctor Abdol rasool Anvaripoor

Position

Anesthesiologist

Other areas of specialty/work

Street address

Post code 7514633341, Bushehr Heart Medical and Educational center, Next to Tamin Ejtemaei Department, After Dadgostari Crossroads, Moalem street, Bushehr

City

Bushehr

Postal code

Person responsible for updating data

Contact

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