

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Clinical trial comparing the sedative effect of Dexmedetomidin infusion versus placebo in the intensive care unit on patients undergoing open heart surgery under cardiopulmonary bypass pump.

Protocol summary

Study aim

compare the efficacy of sedative effect of Dexmedetomidin infusion with placebo in patients undergoing open heart surgery in the intensive care unit

Design

In this double blind clinical trial, 60 patients undergoing open heart surgery under a cardiopulmonary bypass pump, were randomly assigned into two groups of Dexmedetomidine and placebo

Settings and conduct

In this double blind clinical trial, 60 patients undergoing open heart surgery under a cardiopulmonary bypass pump, who were referred to Baqiyatallah Hospital, were randomly assigned randomly into two groups of Dexmedetomidine (group D) and placebo (group P). The medication is prepared by a collaborator, and the investigator and the patient will not be aware of the type of injectable drug.

Participants/Inclusion and exclusion criteria

60 patients undergoing open heart surgery are studied. Emergency patients, patients with liver and renal failure, grade 2 or 3 cardiac block, history of psychiatric disorders, drug addicts and redo surgery are not included in the study.

Intervention groups

In the dexmedetomidine group after completing the operation, doses of dexmedetomidine 1µg/ kg infused over 10 minutes and transferred to the ICU and placed under mechanical ventilation. In ICU, low dose infused doses of 0.2 µg / kg will increase, and the dose will increase to 0.7 µg / kg. In placebo group, normal saline is infused within 10 minutes and transferred to ICU and placed under mechanical ventilation. In ICU, placebo infusion continues. In the two groups, the purpose of sedation is until the patient is mechanically ventilated by Richmond agitation sedation scale (RASS) -2_ + 1 and after extubation of RASS 0.

Main outcome variables

Reduced Delirium, duration of stay in ICU, duration of mechanical ventilation, Dose of midazolam and morphine, incidence of arrhythmia and Increased satisfaction of nurses in the intensive care unit

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161022030421N4**

Registration date: **2019-07-16, 1398/04/25**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-16, 1398/04/25**

Update count: **0**

Registration date

2019-07-16, 1398/04/25

Registrant information

Name

Marzieh Lak

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2244 9013

Email address

marziehlak@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-11, 1398/04/20

Expected recruitment end date

2019-12-26, 1398/10/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial comparing the sedative effect of Dexmedetomidin infusion versus placebo in the intensive care unit on patients undergoing open heart surgery under cardiopulmonary bypass pump.

Public title

The effect of Dexmedetomidin infusion in the intensive care unit

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients referred for coronary artery bypass grafting after obtaining informed consent

Exclusion criteria:

Emergency patients Has a history of liver disease, kidney disease, heart block grade 2 or 3 Systolic blood pressure below 90 mmHg History of psychological disease Use of psychological drugs Opioid addiction Re- surgery

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was stratified using a random table number

Blinding (investigator's opinion)

Double blinded

Blinding description

The medication or placebo is prepared and coded by the co-worker in a 50cc syringe. Each cc of the solution in the syringe contains four micrograms of Dexmedetomidine or a placebo. The patient and the researcher and the specialist nurses will not be informed of the prepared syringe's contents. Researcher will be injected into a patient for 10 minutes from a randomized encoded syringe, equivalent to 1 µg / kg Dexmedetomidine and then the medicine will be infused In a volume equivalent to 0.2 to 0.7 micrograms per kilogram, in accordance with the patient's needs. Upon

completion of the sampling, the co-worker will provide the information about the coding of the syringes.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Baqiyatallah University of Medical Sciences

Street address

Baqiyatallah University of Medical Science, Mollasadra Street, Sheikh Bahaee Street, Tehran, Iran

City

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Postal code

1435917541

Approval date

2019-06-25, 1398/04/04

Ethics committee reference number

IR.BMSU.REC.1398.090

Health conditions studied**1****Description of health condition studied**

Patients undergoing heart surgery with CPP pump.

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes**1****Description**

Incidence of delirium

Timepoint

From the arrival of the patient to the intensive care unit until the patient's discharge from the intensive care unit, the nurse will be evaluated in each shift.

Method of measurement

Confusion assessment method for the ICU (CAM-ICU).

2**Description**

Duration of stay in the intensive care unit

Timepoint

From the arrival of the patient to the intensive care unit until the discharge of the patient from the intensive care unit is evaluated by the unit of the day.

Method of measurement

From the arrival of the patient to the intensive care unit until the discharge of the patient from the intensive care unit is evaluated by the unit of the day.

3

Description

Duration of mechanical ventilation

Timepoint

From the patient's arrival to the intensive care unit until the tracheal tube is removed, in hours

Method of measurement

From the patient's arrival to the intensive care unit until the tracheal tube is removed, in hours

4

Description

Reducing the dose required by morphine and midazolam to achieve desired urination

Timepoint

The patient's arrival in the intensive care unit until the patient's discharge from the intensive care unit is calculated in milligrams.

Method of measurement

The patient's arrival in the intensive care unit until the patient's discharge from the intensive care unit is calculated in milligrams.

5

Description

Incidence of arrhythmia

Timepoint

From the patient's entrance to the intensive care unit until the discharge of the patient from the intensive care unit is assessed by continuous monitoring of electrocardiogram by a specialist nurse.

Method of measurement

From the patient's entrance to the intensive care unit until the discharge of the patient from the intensive care unit is assessed by continuous monitoring of electrocardiogram by a specialist nurse.

6

Description

Assessment of Nurses' satisfaction in ICU

Timepoint

During the period of hospital stay in the intensive care unit by three specialist nurses, using VAS score

Method of measurement

During the period of hospital stay in the intensive care unit by three specialist nurses, using VAS score

Secondary outcomes

1

Description

Changes in blood pressure

Timepoint

From the beginning of the patient's arrival in the intensive care unit until the first six hours, blood pressure was recorded every hour. Then from the sixth hour until the discharge of the patient from the intensive care unit was recorded every 3 hours.

Method of measurement

From the beginning of the patient's arrival in the intensive care unit until the first six hours, blood pressure was recorded every hour. Then from the sixth hour until the discharge of the patient from the intensive care unit was recorded every 3 hours.

2

Description

Heart rate

Timepoint

From the beginning of the patient's arrival in the intensive care unit until the discharge of the patient from the intensive care unit, heart rate was continuously monitored and recorded.

Method of measurement

From the beginning of the patient's arrival in the intensive care unit until the discharge of the patient from the intensive care unit, heart rate was continuously monitored and recorded.

Intervention groups

1

Description

Intervention group: Dexmedetomidine is infused at a dose of 1 µg / kg for 10 minutes and the patient is transferred to the ICU and placed under mechanical ventilation. In ICU, a low dose infusion of 0.2 µg / kg of infusion begins, and, according to the patient's need, the dosage of the drug increases to 0.7 µg / kg for the purpose of achieving Richmond agitation-sedation scale 1-2 + 1. After the extubation condition, the patient is extubated and the dosage of Dexmedetomidine is continued with the aim of achieving RASS 0 (calm and alert).

Category

Treatment - Drugs

2

Description

Control group: after the completion of surgery, placebo (normal saline) is infused over 10 minutes (due to the blindness of the study), and the patient is transferred to the ICU and placed under mechanical ventilation. ICU will find a placebo infusion. In this group, the purpose of sedation is until the patient is mechanically ventilated by RASS -2_ + 1 and after extruding RASS 0.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah hospital

Full name of responsible person

Marzieh Lak

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Baqiyatallah University of Medical Science, Mollasadra Street, Sheikh Bahaee Street, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Mohammad Hasan Kalantar

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k-motamedi@hotmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Marzieh Lak

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Position

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

all collected deidentified IPD

When the data will become available and for how long

starting 1 months after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

for meta analysis

From where data/document is obtainable

from Email

What processes are involved for a request to access data/document

By sending a request to the university Vice-Dean for
Research and obtaining a license

Comments