Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Feb 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 redu surgery are not included in the study.

Intervention groups

In the dexmedmotidine 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
Tehran
Province
Tehran
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 electrochardiogram 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

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

City
Tehran

Province
Tehran

Postal code
1435917541

Phone
+98 21 2244 9013

Email
marziehlak@bmsu.ac.Ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Mohammad Hasan Kalantar

Street address
Baqiyatallah University of Medical Science, Mollasadra Street, Sheikhbahai Street,Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1435915371

Phone
+98 21 8126 3395

Email
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

Street address
Baqiyatallah University of Medical Science, Mollasadra Street, Sheikhbahai Street, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1435915371

Phone
+98 212449013

Email
marziehlak@bmsu.ac.ir

Person responsible for scientific 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

Street address
Baqiyatallah University of Medical Science, Mollasadra Street, Sheikhebahahi Street, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1435915371

Phone
+98 212449013

Email
marziehlak@bmsu.ac.ir

Person responsible for updating data

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
Street address
Baqiyatallah University of Medical Science, Mollasadra Street, Sheikhbahai Street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1435915371
Phone
+98 212449013
Email
marziehlak@bmsu.ac.ir

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