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.lr

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