Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of the effect of sedation with dexmedetomidine and propofol on sleep quality in patients after cardiac surgery

Protocol summary

Study aim
Comparison of the effect of dexmedetomidine and propofol sedation on sleep quality in patients after cardiac surgery
Design
The present study is a randomized clinical trial with parallel design.
Settings and conduct
Sampling will be done in Shahid Rajaei Hospital. Patients are randomly divided into two groups of propofol and dexmedetomidine in the intensive care unit.
Participants/Inclusion and exclusion criteria
Patients over 18 years of age will be included in this study after cardiovascular surgery. These patients will be excluded from the study if they have previously received dexmedetomidine and propofol for initial sedation or an alternative sedative as a primary sedative, have had an organ transplant, or are pregnant or breastfeeding.
Intervention groups
Dexmedetomidine group
Main outcome variables
Sleep quality

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20161127031131N3**
Registration date: **2022-05-09, 1401/02/19**
Registration timing: **retrospective**

Last update: **2022-05-09, 1401/02/19**
Update count: **0**
Registration date
2022-05-09, 1401/02/19

Registrant information

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-05-22, 1400/03/01
Expected recruitment end date
2022-01-20, 1400/10/30
Actual recruitment start date
2021-05-22, 1400/03/01
Actual recruitment end date
2022-01-20, 1400/10/30
Trial completion date
2022-01-20, 1400/10/30

Scientific title
Comparison of the effect of sedation with dexmedetomidine and propofol on sleep quality in patients after cardiac surgery

Public title
Comparison of the effect of dexmedetomidine and propofol on how patients sleep after cardiac surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
cardiovascular surgery aged above 18 years
Exclusion criteria:
If patients received both dexmedetomidine and propofol concomitantly for the primary sedation or an alternative agent as the primary sedation Prior solid organ

transplant Pregnant patients Lactating patients

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **118**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients are randomly assigned to two equal groups and for random assignment, permuted block randomization with quadruple blocks is used.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients participating in the study do not know the group in which they are placed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Shaheed Rajaie Cardiovascular Medical & Research Center

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Tehran

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Postal code

1995614331

Approval date

2021-09-29, 1400/07/07

Ethics committee reference number

IR.RHC.1400.048

Health conditions studied

1

Description of health condition studied

patients with coronary artery disease

ICD-10 code

I24.0

ICD-10 code description

Acute coronary thrombosis not resulting in myocardial infarction

Primary outcomes

1

Description

Evaluation of patient satisfaction with sedation during intubation

Timepoint

The drugs used will start after patients start to wake up, and 4-6 hours before the time of extubation in both groups .The Richmond Agitation and Sedation Scale (RASS) and Mary's Hospital Sleep Questionnaire used the day after operation in ICU.

Method of measurement

The Richmond Agitation and Sedation Scale (RASS) and Mary's Hospital Sleep Questionnaire and vital sign and patients lab data.

Secondary outcomes

1

Description

The effect of sedation on analgesia after extubation

Timepoint

Based on the Richmond Agitation and Sedation Scale (RASS), and Mary's Hospital Sleep Questionnaire (SMHSQ)which is a valid and reliable method for assessing patient sedation in the intensive care unit. And completing the questionnaire the next day.

Method of measurement

Richmond Agitation and Sedation Scale (RASS), and Mary's Hospital Sleep Questionnaire (SMHSQ) and completing a questionnaire on the duration of intubation and intensive care drugs like inoteropes

Intervention groups

1

Description

Control group: Propofol group: in this group we will infuse 50 µg/kg/min propofol in 6 hours (before the time of extubation).The RASS will use to assess patients' levels of sedation in all patients. Evaluation of sleep quality will study using Mary's Hospital Sleep Questionnaire.

Category

Treatment - Drugs

2

Description

Intervention group: Dexmedetomidine group: in this group we will infuse dexmedetomidine (precedex) will 0.5 µg/kg/h in 6 hours (before the time of extubation

).The RASS will use to assess patients' levels of sedation in all patients. Evaluation of sleep quality will study using Mary's Hospital Sleep Questionnaire.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Rajaie Cardiovascular, Medical and Research Center

Full name of responsible person
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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Maryam Ghadimi

Position
Fellowship

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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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

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

Data will be available after the article is published

To whom data/document is available

Information will be available to academic researchers

Under which criteria data/document could be used

Use of information is permitted provided the source is acknowledged

From where data/document is obtainable

Applicants can request the information they need by sending an email

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

Information will be sent to them within one week of sending the email

Comments