Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of dexmedetomidine and propofol for sedation in patients requiring mechanical ventilation in ICU: A randomized clinical trial

Protocol summary

Study aim
Comparison of sedation effects of dexmedetomidine and propofol on patients requiring mechanical ventilation in ICU

Design
Clinical trial with two parallel groups of 35, double-blind, randomized, phase 3 on 70 patients, randomization method with 4 permuted block randomization

Settings and conduct
Patients admitted to the ICU of Ayatollah Rouhani Hospital in Babol, who were included in the study will be divided into two groups, dexmedetomidine and propofol, and receive specified doses of the drug, and the relevant parameters will be recorded during specified time intervals. Patients will be followed up to 24 hours and hemodynamic changes, pain, level of consciousness, etc. will be compared in two groups. On the paper label, random codes are written without a specific order and framework, which is the identification number of the relevant treatment, and the list of which will only be available to the ICU nurse. The evaluator, the statistician, and the patient will be blinded.

Participants/Inclusion and exclusion criteria
patients over 18 years old who need to be intubated and be sedated after surgery and stay in ICU for at least 24 hours.

Intervention groups
Patients will be divided into two groups, dexmedetomidine and propofol, and will receive specified doses of the drug.

Main outcome variables
Need for narcotic drug (fentanyl)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230828059291N1**
Registration date: **2023-09-09, 1402/06/18**
Registration timing: **prospective**

Last update: **2023-09-09, 1402/06/18**
Update count: **0**

Registration date
2023-09-09, 1402/06/18

Registrant information

Name
Amir hossein Saadati

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 911 754 2722

Email address
asaadati1997@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-14, 1402/06/23

Expected recruitment end date
2023-10-12, 1402/07/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of dexmedetomidine and propofol for sedation in patients requiring mechanical ventilation in ICU: A randomized clinical trial

Public title
comparison of dexmedetomidine and propofol sedation

in ICU

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients over 18 years old staying in ICU for at least 24 hours after surgery need to be intubated and be sedated

Exclusion criteria:

Hypotension (SBP<90) pregnant women obesity (body weight more than 50% higher than ideal body weight) ESRD patients Glasgow Coma Scale (GCS) below 12 (moderate and severe brain damage) Significant arrhythmia or high degree of atrioventricular node block patients who are allergic to the drugs

Age

From **18 years** old

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: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is Permuted Block Randomization, which is set as blocks of 4 (AABB). Then, using Excel software, a number is randomly assigned to each of the letters in the block, and then the letters A and B are arranged based on the size of the number that came randomly and form a random sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

The list of random allocation of patients will only be available to the ICU nurse. In order to hide the random assignment process, random codes are written on the paper label without a specific order and frame, which is the identification number of the relevant treatment, and the list will be available only to the ICU nurse. The labels will be stuck on the medicine packages in the order of the randomization list. Medicine packages will be arranged in the order of the randomization list inside the box. When the doctor declares the eligibility of a patient, the nurse will provide the patient with the treatment package. The person evaluating the intended outcomes is a third person who is unaware of the randomization process and the type of treatment performed. In order to analyze the data, a statistician who is separate from the study process and is unaware of all the processes will be used.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Ganjafrooz Street, Babol University of Medical Sciences

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶۴۷۷۴۵

Approval date

2023-08-27, 1402/06/05

Ethics committee reference number

IR.MUBABOL.HRI.REC.1402.071

Health conditions studied

1

Description of health condition studied

Sedation in ICU patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

comparison of the need for narcotic drug (fentanyl) in dexmedetomidine and propofol groups

Timepoint

The amount of injected fentanyl will be measured at the end of 24 hours.

Method of measurement

The amount of fentanyl injection will be recorded during the study.

Secondary outcomes

1

Description

Hemodynamic parameters (systolic and diastolic blood pressure, heart rate, mean arterial blood pressure)

Timepoint

Hemodynamic parameters will be recorded at intervals of 30 minutes, 1 hour, 3 hours, 6 hours, 12 hours and 24 hours.

Method of measurement

The monitoring device

2

Description

Respiratory parameters (respiratory rate, spontaneous breathing and airway pressure)

Timepoint

Respiratory parameters will be recorded at intervals of 30 minutes, 1 hour, 3 hours, 6 hours, 12 hours and 24 hours.

Method of measurement

The mentioned variables are measured by ventilator devices and then recorded at the time intervals.

3

Description

Level of consciousness

Timepoint

The level of consciousness will be recorded at intervals of 30 minutes, 1 hour, 3 hours, 6 hours, 12 hours and 24 hours.

Method of measurement

The level of consciousness will be measured by Ramsay Sedation Scale.

Intervention groups

1

Description

Intervention group 1: Group A will receive Ḍexmedetomidine with a loading dose of 1 µg/kg for 10 minutes followed by a maintenance infusion of 5 µg/kg/hr (0.2-0.7 µg/kg/hr). If the target level of RSS (4 and 5) was not obtained or maintained; A propofol bolus of 0.2 mg/kg will be injected for a maximum of three consecutive boluses at an interval of 3 to 5 minutes.

Category

Treatment - Drugs

2

Description

Intervention group 2: Group B will receive Propofol with an infusion of 2 mg/kg/hr (1-3 mg/kg/hr). If the target level of RSS (4 and 5) is not achieved or maintained; A propofol bolus of 0.2 mg/kg will be injected for a maximum of three consecutive boluses at an interval of 3 to 5 minutes.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol Ayatollah Rouhani Hospital

Full name of responsible person

Amirhossein Saadati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

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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

Babol 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
Babol University of Medical Sciences
Full name of responsible person
Amir Hossein Saadati
Position
Medical student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Information about the study will be published.
When the data will become available and for how long
End of the study
To whom data/document is available
The documentation will be accessible to everyone.
Under which criteria data/document could be used
No special conditions are considered.
From where data/document is obtainable
asaadati1997@gmail.com
What processes are involved for a request to access data/document
There is no special process.
Comments