Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of midazolam with dexmedetomidine before extubation on anesthesia emergence reactions in patients after lumbar disc surgery: a randomized clinical trial study

Protocol summary

Study aim

Comparison of the effect of midazolam with intravenous dexamethasone before extubation on anesthesia withdrawal reactions in patients after lumbar disc surgery

Design

The present study is a double-blind randomized clinical trial.

Settings and conduct

In the present study, the drug injection will be 20 minutes before the start of the extubation process. Induction of anesthesia and induction will be the same in all patients and maintenance of anesthesia in all patients will be by TIVA (propofol + remifentanil). Doses of dexmedetomidine and midazolam will be injected in the study groups after surgery and 20 minutes before extubation while the patient is still in the prone position.

Participants/Inclusion and exclusion criteria

All patients who are candidates for lumbar disc surgery referred to Peymaniyeh Hospital in Jahrom in 1401-1400, aged between 18 and 65 years, who are fully satisfied with the study; Do not have a history of smoking or alcohol; do not have uncontrolled cardiovascular disease, diabetes, or obesity; have no history of hypertension, asthma or chronic obstructive pulmonary disease.

Intervention groups

Patients will be randomly divided into three groups A (receiving midazolam at a dose of 0.20 mg / kg / h) (39) and B (receiving dexmedetomidine at a dose of 1 µg / kg) (39) And c will be used as the control group (placebo = normal saline).

Main outcome variables

After drug injection, systolic and diastolic blood pressure and mean arterial and heart rate, before and after extubation will be recorded. In the recovery phase until the patient is discharged from the care unit after anesthesia, vital signs will be recorded before extubation, 5 minutes after extubation, when entering the recovery, 5 minutes after entering the recovery and 10 minutes after recovery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210415050976N2**
Registration date: **2021-05-25, 1400/03/04**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-25, 1400/03/04**
Update count: **0**

Registration date

2021-05-25, 1400/03/04

Registrant information

Name

navid kalani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5433 6085

Email address

k.navid@juma.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of midazolam with dexmedetomidine before extubation on anesthesia emergence reactions in patients after lumbar disc surgery: a randomized clinical trial study

Public title
midazolam with dexmedetomidine for extubation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Candidates for lumbar disc surgery referred to Peymaniyeh Hospital in Jahrom Complete satisfaction to participate in the study No smoking and alcohol Lack of uncontrolled cardiovascular disease and diabetes and obesity No history of hypertension, no history of asthma and chronic obstructive pulmonary disease Age between 18 and 65 years
Exclusion criteria:
occurrence of symptoms indicating an airway problem Risk factor for aspiration Recent airway infection Bmi above 30
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients participating in the present study will be divided into three groups of dexmedetomidine, midazolam and control by throwing dice
Blinding (investigator's opinion)
Double blinded
Blinding description
After preparation, the drugs are placed in a special box in a syringe and delivered to the relevant anesthesiologist. The anesthesiologist is already aware of the grouping of studies and the safety of injecting all three available box models (three study groups) but does not know the contents of the received box. There will be no difference in how the contents of the three study boxes are injected. Only the anesthesia supervisor will be notified of the coding of the boxes. The outcome assessor will have no information about the type of drug.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of jahrom University of Medical Sciences
Street address
Jahrom, Motahhari Blvd, Jahrom University of Medical Sciences
City
jahrom
Province
Fars
Postal code
7167758256
Approval date
2021-03-03, 1399/12/13
Ethics committee reference number
IR.JUMS.REC.1399.140

Health conditions studied

1

Description of health condition studied
Lumbar disc surgery
ICD-10 code
M43.06
ICD-10 code description
Spondylolysis, lumbar region

Primary outcomes

1

Description
vital signs
Timepoint
Before the extubation, 5 minutes after extubation, when entering recovery room, 5 and 10 minutes after recovery
Method of measurement
Monitoring device

Secondary outcomes

1

Description
Occurrence of cough
Timepoint

During and after extubation

Method of measurement

Likert scale for measuring cough (no cough = 0, mild cough = 1, moderate cough = 2 and severe cough = 3).

2

Description

nausea and vomiting

Timepoint

During and after extubation

Method of measurement

Likert spectrum for measuring nausea (no nausea = 0, no nausea = 1 and no vomiting = 2)

Intervention groups

1

Description

Intervention group 1: Patients in group 1 will receive midazolam 20 minutes before extubation at a dose of 20. mg per kg of body weight.

Category

Treatment - Drugs

2

Description

Intervention group 2: Patients in group 2 will receive dexmedetomidine 20 minutes before extubation at a dose of 1 mg per kg body weight.

Category

Treatment - Drugs

3

Description

Control group: Patients in the control group will receive normal saline 20 minutes before extubation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Peymaniyeh Hospital of Jahrom city

Full name of responsible person

Navid Kalani

Street address

Jahrom, Shahid Motahari Boulevard, Peymanieh Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Kavous solh jo

Street address

Shahid Motahari Boulevard, Jahrom University of Medical Sciences, Jahrom

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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

Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

Navid Kalani

Position

Expert in Clinical Research Development Center

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Jahrom University of Medical Sciences
Full name of responsible person
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Position
Expert in Clinical Research Development Center
Latest degree
Master
Other areas of specialty/work
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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
At the reasonable request of the person in charge of this project, the data obtained from the project will be available.
When the data will become available and for how long
After the publication of the article or dissertation resulting from this research
To whom data/document is available
People who send their request to the person in charge of this project.
Under which criteria data/document could be used
After the publication of the article or dissertation of this study, the data of this research will be available to researchers who intend to conduct meta-analytical review studies.
From where data/document is obtainable
If the request is sent by email to the person in charge of this research, the request will be reviewed.
What processes are involved for a request to access data/document
If all the collaborating researchers in this research are approved and the research assistant is approved, the data will be provided to the applicant.
Comments