Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparing the effect of dexmetedomidine and remifentanil on controlled hypotension in patients undergoing general anesthesia candidates for spine surgery

Protocol summary

Study aim
Blood pressure management during surgery

Design
A double-blind clinical trial in two groups of dexmedetomidine and remifentanil (35 people in each group) randomly based on random numbers generated using Random Allocation computer software.

Settings and conduct
Patients in Imam Khomeini Hospital will be randomly divided into two groups: dexmedetomidine and remifentanil. The patient and the trained technician will be responsible for recording the patients' data and will not be informed about the grouping of the drugs used. The dose of remifentanil and dexmedetomidine (1-0.1) micrograms/kg of body weight per minute until the end of the surgery will be nitroglycerin (TNG) infusion at the rate of 5 micrograms per minute so that the patient's blood pressure reaches the range of SBP between 80-100 mm Hg. More than 20 At first, the base percentage of propofol will be reduced by the same amount, and if necessary, the dose of dexmedetomidine or remifentanil will be reduced in two groups with the same protocol.

Participants/Inclusion and exclusion criteria
Entering into the study adult patients with ASA I-II status undergoing spine surgery under anesthesia and not including patients who need emergency surgery, pregnant people, patients with a history of spine surgery, history of opioid use, drug abuse or alcohol addiction, history nervous diseases, Neuromuscular or psychiatric (especially history of seizures or epilepsy), history of heart failure, patients with cardiac bradycardia, long-term and chronic use of painkillers including cyclooxygenase 2 inhibitors, patients with unpredictable events Heavy bleeding

Intervention groups
Dexmedetomidine group and Remifentanil group

Main outcome variables
Hypotension control in spine surgery patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241108063640N2**
Registration date: **2024-11-15, 1403/08/25**
Registration timing: **prospective**

Last update: **2024-11-15, 1403/08/25**
Update count: **0**

Registration date
2024-11-15, 1403/08/25

Registrant information

Name
hadi Hooshyar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 44 3346 9931

Email address
hooshyarhadi@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-12-20, 1403/09/30

Expected recruitment end date
2025-09-21, 1404/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effect of dexmetedomidine and remifentanil on controlled hypotension in patients undergoing general anesthesia candidates for spine surgery

Public title
Comparing the effect of dexmetedomidine and remifentanil on controlled hypotension in patients undergoing general anesthesia candidates for spine surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Inclusion criteria included adult patients with ASA I-II status undergoing spine surgery under general anesthesia Completion of the informed consent form for participating in the study

Exclusion criteria:
Patients who need emergency surgery Pregnant people Patients with a history of spine surgery History of opioid use Drug abuse or alcohol addiction History of neurological diseases Neuromuscular or psychiatric (especially history of seizures or epilepsy) History of heart failure patients with cardiac bradycardia Long-term and chronic use of pain relievers, including cyclooxygenase 2 inhibitorsPatients with unpredictable events such as severe bleeding

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly divided into two groups based on random numbers generated using Random Allocation computer software.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient and the trained technician are responsible for recording the patients' data and will not be informed about the grouping of the drugs used.

Placebo
Not used

Assignment
Parallel

Other design features
. Adult patients with ASA I-II status undergoing spinal surgery under general anesthesia in Imam Khomeini Hospital Urmia will be included in the study. Then the patients will be divided into two groups of dexmedetomidine and remifentanil (35 people in each group) using the table of random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Imam Khomeini Hospital

Street address
Imam Khomeini University Hospital-Ershad AVE-Modarres Blvd- Urmia

City
Urmia

Province
West Azarbaijan

Postal code
5715789397

Approval date
2024-10-02, 1403/07/11

Ethics committee reference number
IR.UMSU.HIMAM.REC.1403.084

Health conditions studied

1

Description of health condition studied
Adult patients with ASA I-II status undergoing spine surgery under general anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Systolic and diastolic blood pressure control

Timepoint
(before induction), t1 (after induction), t2 (after incision), t3 (15 minutes after surgery), t9 (90 minutes after surgery), R0 (entering the recovery room) and R30 (30 minutes after from entering the recovery room)

Method of measurement
by a non-invasive sphygmomanometer for anesthesia monitoring

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Dexmedetomidine group
Category
Treatment - Drugs

2

Description
Intervention group: Fentanyl withdrawal group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Urmia
Full name of responsible person
Dr.Hadi hooshyar
Street address
Imam Khomeini University Hospital-Ershad AVE-Modarres Blvd- Urmia
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Saber Gholizadeh
Street address
Resalat Boulevard - Emergency Alley - Urmia University of Medical Sciences
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Email
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Web page address
https://Umsu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Dr.Hadi Hooshyar
Position
assistant professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Latest degree

Specialist

Other areas of specialty/work
Anesthesiology

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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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available