

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the effect of dexmedetomidine and remifentanyl on controlled hypotension in patients undergoing general anesthesia candidates for spine surgery

#### Protocol summary

Hypotension control in spine surgery patients

##### Study aim

Blood pressure management during surgery

##### Design

A double-blind clinical trial in two groups of dexmedetomidine and remifentanyl (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 remifentanyl. 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 remifentanyl 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 remifentanyl 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 Remifentanyl group

##### Main outcome variables

#### 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 dexmedetomidine and remifentanyl on controlled hypotension in patients undergoing general anesthesia candidates for spine surgery

## Public title

Comparing the effect of dexmedetomidine and remifentanyl 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 inhibitors Patients 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 remifentanyl (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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#### Postal code

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#### Phone

+98 44 3346 9931

#### Email

hooshyarhadi@gmail.com

#### Web page address

http://Imam.umsu.ac.ir

## 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

#### City

Urmia

#### Province

West Azarbaijan

#### Postal code

5718748983

#### Phone

+98 44 3237 5907

#### Email

sabergholizadeh@yahoo.com

#### 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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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Oroumia University of Medical Sciences

#### Full name of responsible person

Dr.Hadi Hooshyar

#### Position

assistant professor

#### Latest degree

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**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

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Oroumia University of Medical Sciences

**Full name of responsible person**

Dr.Hadi Hooshyar

**Position**

assistant professor

**Latest degree**

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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