

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison the effect of dexmedetomidine with remifentanil on postoperative pain after lumbar laminectomy with general anesthesia

Protocol summary

Study aim

The purpose of this study will be to assess comparison the effect of dexmedetomidine with remifentanil on postoperative pain after lumbar laminectomy with general anesthesia

Design

Clinical trial with two arm parallel groups, randomised trial with double blinded assessment. Study phase will be 3-2.

Settings and conduct

In Urmia Imam Khomeini hospital operating room, pain score will be measured by visual analog scale, whose utilization will be previously taught to the patient recovery, as well as 6, 12, and 24 hours after surgery by trained nurses who will be unaware of the group of each patient.

Participants/Inclusion and exclusion criteria

inclusion criteria: age group of 20 to 60 years old, American Society of Anesthesiologists class I and II, elective lumbar laminectomy exclusion criteria: hypertension, history of bradycardia (heart rate below 50), those who had allergies to the used medications, gastritis, kidney and lung disease, psychiatric problems, drug addicts, and patients treated with beta-blockers, methyldopa, monoamine oxidase inhibitors, analgesic drugs, and those with body mass index above 25 kg/m²

Intervention groups

Intervention group dexmedetomidine: Before anesthesia induction, 0.3 µg/50kg/min dexmedetomidine will be injected using a syringe pump for 10 minutes. During surgery 0.01 to 0.02 µg/kg/min dexmedetomidine will be used. Intervention group remifentanil: Before anesthesia induction, 0.01 µg/kg/min remifentanil will be injected using a syringe pump for 10 minutes. During surgery 0.01 to 0.2 µg/kg/min remifentanil will be used.

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160430027677N13**

Registration date: **2019-02-24, 1397/12/05**

Registration timing: **retrospective**

Last update: **2019-02-24, 1397/12/05**

Update count: **0**

Registration date

2019-02-24, 1397/12/05

Registrant information

Name

Shahryar Sane

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3223 4897

Email address

sane.sh@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-20, 1396/10/30

Expected recruitment end date

2018-05-21, 1397/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of dexmedetomidine with remifentanil on postoperative pain after lumbar laminectomy with general anesthesia

Public title

Evaluation the effect of dexmedetomidine and remifentanil on postoperative pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age group of 20-60 years old American Society of Anesthesiologists class I and II elective lumbar laminectomy

Exclusion criteria:

Patients with hypertension History of heart disease Bradycardia (Heart rate less than 50 per minute) arrhythmia People who have allergies to drugs used Gastritis Renal and pulmonary disease mental health problems Drug addict Patients treated with beta-blockers, methyl dopa, monoamine oxidase inhibitors Pain medications Body mass index greater than 25 kg/m²

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned into two groups of Dexmedetomidine (group D) and Remifentanil (group R) using Random Allocation Software 2.0, and the target codes will be written and placed in sealed envelopes with sequential allocation using double-blind method.

Blinding (investigator's opinion)

Double blinded

Blinding description

The anesthesiologist will be unaware of which patient will be assigned to which group. Syringes will be identical and only the nurse will know about the contents of each of them, and finally, after collecting information from the anesthesia residents, the anesthesiologist will be informed of the group each patient will be assigned to.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Emergent Street, Ershad Avenue

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2017-12-13, 1396/09/22

Ethics committee reference number

IR.UMSU.REC.1396.290

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

R52.9

ICD-10 code description

Generalized pain NOS

Primary outcomes

1

Description

pain

Timepoint

In recovery, 6, 12 and 24 hours after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

The average need for an analgesic drug to control pain

Timepoint

In 12 hours after surgery

Method of measurement

milligram

2

Description

Mean Arterial Blood Pressure

Timepoint

time of laryngoscopy and during surgery

Method of measurement

None Invasive Blood Pressure

3

Description

Mean pulse Rate

Timepoint

time of laryngoscopy and during surgery

Method of measurement

Electrocardiogram

Intervention groups

1

Description

Intervention group: Before anesthesia induction, 0.3 µg/50kg/min dexmedetomidine will be injected using a syringe pump for 10 minutes. During surgery 0.01-0.02 µg/kg/min dexmedetomidine will be used.

Category

Treatment - Drugs

2

Description

Intervention group: Before anesthesia induction, 0.01 µg/kg/min remifentanyl will be injected using a syringe pump for 10 minutes. During surgery 0.01 to 0.2 µg/kg/min remifentanyl will be used.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini Hospital, C operating room

Full name of responsible person

Shahryar Sane

Street address

Modarres Boulevard, Ershad Boulevard

City

Uemia

Province

West Azarbaijan

Postal code

5715781351

Phone

+98 44 3346 9931

Fax

+98 44 3346 8967

Email

sanesh@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

Street address

Emergent Street, Ershad Avenue

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Fax

+98 44 3223 4897

Email

research@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

Shahryar Sane

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Emergrnt Street, Resalat Blvd

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Email

sanesh@umsu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Shahryar Sane

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Emergrnt Street, Resalat Boulevard

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Fax

+98 44 3346 8967

Email

sanesh@umsu.ac.ir

Other areas of specialty/work

Anesthesiology

Street address

Emergent Street, Ershad Blvd

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Fax

+98 44 3346 8967

Email

sanesh@umsu.ac.ir

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

Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Shahryar Sane

Position

Associate professor

Latest degree

Subspecialist