Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Comparison the effect of dexmedetomidine with remifentanil on postoperative pain after lumbar laminecthomy 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 0.01to 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 0.01to 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 laminecthomy with general anesthesia

Public title
Evaluation the effect of dexmedetomidine and remifentanil on posoperative 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 knew 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 commitee 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 remifentanil will be injected using a syringe pump for 10 minutes. During surgery 0.01to 0.2 µg/kg/min remifentanil 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
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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
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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
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Person responsible for scientific inquiries

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Full name of responsible person
Shahryar Sane

Position
Associate professor

Latest degree
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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
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