

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Comparison of Hemodynamic Changes and Side Effects Due to Two Methods of General Anesthesia and Epidural Anesthesia in Patients Undergo Lumbar Laminectomy Surgery

Protocol summary

Summary

Objectives: In the present study, we compare the usage of two methods for anesthesia (general anesthesia and epidural anesthesia) to find the method with less hemodynamic changes and side effects due to anesthesia in patients undergo lumbar laminectomy.

Design: In this clinical trial 60 patients who are candidate for lumbar laminectomy surgery will be randomly divided into two groups (group 1 and 2). **Setting and conduct:** The patients in group 1 will receive Midazolam and Fentanyl intravenously for anesthesia induction, then will be intubated using direct intratracheal method. Patients in group 2 will receive epidural injection of Lidocain for spinal anesthesia. **Major Inclusion and Exclusion Criteria:** Patients who are candidate for lumbar laminectomy who are categorized in ASA class 1 in NPO condition, without underline diseases or presence of epidural anesthesia contraindications. **Intervention:** Usage of two methods of general anesthesia or epidural anesthesia. **Main Outcome Measures (variables):** Finally, mean heart rate, blood pressure, presence of nausea and vomiting and postoperative pain will be compared with each other in patients of the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015030419037N7**
Registration date: **2015-03-15, 1393/12/24**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-03-15, 1393/12/24

Registrant information

Name

Mahdieh Yousef-Zanjani

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 6004

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yusefi.mahdieh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2015-04-21, 1394/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Hemodynamic Changes and Side Effects Due to Two Methods of General Anesthesia and Epidural Anesthesia in Patients Undergo Lumbar Laminectomy Surgery

Public title

Comparison of the Effects of Two Methods of General Anesthesia and Epidural Anesthesia During Lumbar Laminectomy Surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients between 30 to 60 years of age who are candidate for lumbar laminectomy surgery and are categorized in ASA class 1 (The American Society of Anesthesiologists Physical Status classification system): Normal healthy patients with no organic, physiologic, or psychiatric disturbance. Exclusion criteria: Patients who use anti-hypertensive, analgesic or sedative agents; patients who are not NPO (nil per os); no patient's tendency for epidural anesthesia; obesity; presence of epidural anesthesia contraindications.

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

In this study, eligible patients will be entered randomly into the trial groups by usage of colored carts.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qazvin University of Medical Sciences

Street address

Shahid-Bahonar Boulevard

City

Qazvin

Postal code

Approval date

2014-06-12, 1393/03/22

Ethics committee reference number

28.20.8852

Health conditions studied

1

Description of health condition studied

Heart rate instability due to anesthesia

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Blood pressure instability due to anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mean heart rate

Timepoint

From the beginning of anesthesia every 5 minutes until 1 hour after surgery

Method of measurement

Monitor device

2

Description

Mean blood pressure

Timepoint

From the beginning of anesthesia every 5 minutes until 1 hour after surgery

Method of measurement

Monitor device

Secondary outcomes

1

Description

Post operation pain

Timepoint

From the beginning of surgery every 2 hours until 6 hours after the surgery

Method of measurement

Visual Analogue Scale questionnaire (VAS)

2

Description

Nausea and vomiting

Timepoint

During recovery time

Method of measurement

Objective

Intervention groups

1

Description

First intervention group: Intravenously injection of Midazolam (Ampoule 5 mg/ml from Aburaihan drug manufacturing company, Iran) (0.1 to 0.3 mg/kg) and Fentanyl (Ampoule 50 from Pharmaceutical drug manufacturing company, Belgium) (1/5 µg/kg) for anesthesia induction and then direct intratracheal intubation.

Category

Treatment - Other

2

Description

Second intervention group: Epidural injection of Lidocain (Ampoule 20 mg/ml from Aburaihan drug manufacturing company, Iran) (2-3 ml) for spinal anesthesia using 25 Gauge Quincke spinal needle in L3-L4 or L4-L5 epidural spaces.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid-Rajayi Hospital

Full name of responsible person

Dr. Arezou Aghaali

Street address

Padegan Boulevard

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Investigator

Full name of responsible person

Dr. Arezou Aghaali

Street address

Shahid-Bahonar Boulevard

City

Qazvin

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Investigator

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Masoumeh Hosseyni Valami

Position

Anesthesiologist, Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Arezou Aghaali

Position

Anesthesiology Resident

Other areas of specialty/work

Street address

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty
Analytic Code
empty
Data Dictionary
empty