

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Comparative study of hemodynamic changes, amount of bleeding, satisfaction of surgeon and patient in the use of two drugs, Midazolam and Dexmedetomidin, in laminectomy surgery under spinal anesthesia

Protocol summary

Study aim

Investigation of the effect of Midazolam and Dexmedetomidine injection on the effects of laminectomy under spinal anesthesia

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 105 patients. Simple randomization tables are used for randomization

Settings and conduct

This study is a randomized double-blind clinical trial with a control group, the target population of which will be candidates for spinal laminectomy under spinal anesthesia at Al-Zahra Medical Center in Isfahan. Patients are distributed in three groups by simple random sampling. After placing on the operating table and performing spinal anesthesia on each group, one of the injected drug interventions, vital signs, and hemodynamic status of the patient before, during, and after surgery are controlled and recorded. Interventional groups are coded, so the injector, clinical caregiver, surgeon, and patient are unaware of the injected intervention and are blind.

Participants/Inclusion and exclusion criteria

Patients between the ages of 18 and 65 who are candidates for laminectomy under spinal anesthesia who are in the ASA class of anesthesia I and II and do not have a specific underlying problem can enter the study.

Intervention groups

After the patient is placed on the operating table and connected to standard monitors, the patient undergoes spinal anesthesia. Then, in group A patients, 0.2 mg/kg / h of Midazolam was given, in group B patients, 0.1 µg / kg / h Dexmedetomidine, and in group C patients, 50 cc of normal saline will be infused per hour.

Main outcome variables

Blood Pressure; Heart Rate; Oxygen Saturation; Bleeding Rate; Surgeon satisfaction; Patient satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160307026950N22**

Registration date: **2020-07-21, 1399/04/31**

Registration timing: **prospective**

Last update: **2020-07-21, 1399/04/31**

Update count: **0**

Registration date

2020-07-21, 1399/04/31

Registrant information

Name

Behzad Nazemroaya

Name of organization / entity

Isfahan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of hemodynamic changes, amount of bleeding, satisfaction of surgeon and patient in the use of two drugs, Midazolam and Dexmedetomidin, in laminectomy surgery under spinal anesthesia

Public title

Evaluation of the effect of Midazolam and Dexmedetomidine in Laminectomy surgery under spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients are candidates for laminectomy surgery under spinal anesthesia Age range 18 to 65 years old ASA class I and II anesthesia The patient's consent to participate in the study

Exclusion criteria:

Unstable hemodynamic at the beginning of the operation (systolic pressure less than 90, diastolic less than 60 and heart rate less than 60) Taking medications that affect the hemodynamic status Taking anticoagulants

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization in this study is simple and using a randomization table so that 105 patients with entry conditions are selected and each is given a three-digit code and these codes are entered in the table and then for each From the intervention groups, we randomly select 35 patients using these codes from the table.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drugs and placebo are prepared and coded in the same way. The patient, the injecting specialist, the surgeon, and the respondent are unaware of the contents of the injected drug and are blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar jarib street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2018-06-23, 1397/04/02

Ethics committee reference number

IR.MUI.MED.REC.1397.240

Health conditions studied

1

Description of health condition studied

Laminectomy surgery

ICD-10 code

G99

ICD-10 code description

Other disorders of nervous system in diseases classified elsewhere

Primary outcomes

1

Description

Systolic Blood Pressure

Timepoint

Before surgery, after spinal anesthesia, 20 minutes after the Intervention injection and then every 30 minutes until the end of recovery.

Method of measurement

Non-invasive blood pressure measurement

2

Description

Diastolic Blood Pressure

Timepoint

Before surgery, after spinal anesthesia, 20 minutes after the Intervention injection and then every 30 minutes until the end of recovery.

Method of measurement

Non-invasive blood pressure measurement

3

Description

Heart Rate

Timepoint

Before surgery, after spinal anesthesia, 20 minutes after the Intervention injection and then every 30 minutes until the end of recovery.

Method of measurement

ECG monitoring

4

Description

Oxygen saturation

Timepoint

Before surgery, after spinal anesthesia, 20 minutes after the Intervention injection and then every 30 minutes until the end of recovery.

Method of measurement

Pulse oximeter

5

Description

Surgeon Satisfaction

Timepoint

After surgery

Method of measurement

Ask the surgeon

6

Description

Patient Satisfaction

Timepoint

After surgery

Method of measurement

Ask the patient

7

Description

Bleeding Rate

Timepoint

After surgical incision until the end of recovery

Method of measurement

Observing

Secondary outcomes

1

Description

Nausea

Timepoint

Every 30 minutes after entering recovery

Method of measurement

Ask the patient

2

Description

Vomiting

Timepoint

Every 30 minutes after entering recovery

Method of measurement

Ask the patient

3

Description

Rate of Postoperative pain

Timepoint

Every 30 minutes after entering recovery

Method of measurement

Ask the patient

Intervention groups

1

Description

Intervention Group A: Patients receive 0.2 mg of Midazolam per kilogram of body weight per hour after spinal anesthesia.

Category

Treatment - Drugs

2

Description

Intervention Group B: Patients receive 0.1 micro grams of Dexmedetomidine per kilogram of body weight per hour after spinal anesthesia.

Category

Treatment - Drugs

3

Description

Control group C: Patients receive 50 ml of normal saline per hour after spinal anesthesia.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Isfahan Alzahra hospital

Full name of responsible person

Behzad Nazem roaya

Street address

Soffeh boulevard, Shahid Keshvari highway

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Vice Chancellor for Research, Isfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Mottahareh Rajabi Moghaddam

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Position

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Latest degree

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Bachelor

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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