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 Dexmedetomedin, 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

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Behzad Nazemroaya
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Isfahan University of Medical Sciences
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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 Dexmedetomedin, 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

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Isfahan

Province
Isfehan

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
Laminctomy 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
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Sponsors / Funding sources

1

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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
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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