

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of general anesthesia and spinal on laminectomy

Protocol summary

Summary

(1) Objectives: The propose of this study is assess the competitive effect of general anesthesia verses spinal on outcome after laminectomy (2) Design: The statistical population included patients under laminectomy and sample size was 50. In a randomized blind clinical trial with seal envelop method, the patients will be assigned 2 group: general or spinal anesthesia. This study is phase 2. (3) Setting and conduct: Patients after general anesthesia or spinal under laminectomy. (4) Participants: Inclusion criteria included: age 18-65 year , same surgeon and anesthesia. The exclusion criteria included: lack of patient agreement for spinal anesthesia, systemic disease, reaction of spinal anesthesia drug. (5) Intervention: in general anesthesia group with isofluran, o2 50%, N2 o 50% in maintenance of anesthesia and in spinal group with bupivacaine 5% intrathecally at L3 - L4 or L4 - L5 space in the sitting position were included in the study.(6) main outcome measures: pain, hemodynamic change, shivering, nausea and vomiting , drug consumption, surgeon and patients satisfaction, length of stay and the first movement time will be assessed with checklist.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015062222870N1**
Registration date: **2015-09-21, 1394/06/30**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-21, 1394/06/30

Registrant information

Name

Ali Khani

Name of organization / entity

Ilam University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Ilam University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of general anesthesia and spinal on laminectomy

Public title

The comparison effect of general anesthesia verses spinal on outcome of laminectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 18-65 year; same surgeon and anesthesia. Exclusion criteria: lack of patient agreement for spinal anesthesia; systemic disease; reaction of spinal anesthesia drug.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **50****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

with seal envelop method, the patients assigned 2 group.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ilam University of Medical Sciences

Street address

Pajohesh Blvd, Banganjab, Ilam

City

Ilam

Postal code**Approval date**

2015-06-15, 1394/03/25

Ethics committee reference number

IR.MEDILAM.EC/94/H/279-18/3/1394

Health conditions studied**1****Description of health condition studied**

laminectomy

ICD-10 code

M99

ICD-10 code description

vertebral column

Primary outcomes**1****Description**

shivering

Timepoint

After intervention in recovery

Method of measurement

checklist and VAS

2**Description**

Bleeding

Timepoint

During intervention in surgery time

Method of measurement

Pad

3**Description**

Pain

Timepoint

After intervention during 1,4,8,12,24 h after surgery

Method of measurement

Visual Analogue Scale (VAS)

4**Description**

Nausea & Vomiting

Timepoint

After intervention in recovery

Method of measurement

Checklist

5**Description**

Blood pressure

Timepoint

During intervention under surgery

Method of measurement

sphygmomanometer

6**Description**

Hart rate

Timepoint

During intervention under surgery

Method of measurement

Pulse oximeter

Secondary outcomes**1****Description**

cost

Timepoint

After intervention during discharge

Method of measurement

checklist

2**Description**

drug consumption
Timepoint
during 24 h after intervention
Method of measurement
according to Mg

3

Description
surgeon satisfaction
Timepoint
After intervention
Method of measurement
Questionnaire

4

Description
patients satisfaction
Timepoint
After intervention
Method of measurement
Questionnaire

5

Description
The first movement time
Timepoint
After intervention
Method of measurement
according to time duration after surgery

6

Description
Length of hospital stay
Timepoint
After intervention
Method of measurement
according to time duration of stay

7

Description
duration of recovery room
Timepoint
After intervention
Method of measurement
according to time duration

Intervention groups

1

Description
Intervention group 2: In spinal group patients using bupivacaine 5% , 15 mg intrathecally at L3 - L4 or L4 - L5 space in the sitting position were included in the study . bupivacaine manufacturer, is Aboureyhan
Category
Treatment - Drugs

2

Description
Intervention group 1: In general anesthesia group using propofol (2-3 Mg/Kg), 50% O2, 50% N2o, fentanyl, isoflurane and atracurium patients was undergoing surgery. propofol,fentanyl and isoflurane manufacturer, is Aboureyhan
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Ali Khani
Street address
Shahid Beheshti Bolvar, Imam Khomeini Hospital, Ilam
City
Ilam

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Ilam University of Medical Sciences
Full name of responsible person
Dr Koroosh Soleimannejad
Street address
Pajohesh Bolvd, Banganjab, Ilam
City
Ilam
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Ilam University of Medical Sciences
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

Ilam University of Medical Sciences

Full name of responsible person

Ali Khani

Position

MSc of Nursing

Other areas of specialty/work**Street address**

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Fax

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