Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Sevoflurane and Propofol on complications after laminectomy

Protocol summary

Summary

The propose of this study is assess to competitive effect of Sevoflurane versus propofol on hemodynamic changes and complications after laminectomy during the year 2015. The statistical population included patients candied of laminectomy and sample size is 75. Inclusion criteria: age 20-70, same surgeon and anesthesia. The exclusion criteria included: systemic disease. In a randomized double blind clinical trial, the patients assigned 3 group: Sevoflurane, propofol and Sevoflurane Pulse propofol. The parameters of pain, hemodinamic change, shivering, nausea and vomiting, drug consumption and recovery duration was assessed with checklist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015071122870N2**
Registration date: **2015-07-27, 1394/05/05**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-07-27, 1394/05/05

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

2015-08-23, 1394/06/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Sevoflurane and Propofol on complications after laminectomy

Public title

The compartion effect of Sevoflurane versus Propofol on hemodynamic changes and complications after laminectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients candidate for laminectomy; age 20-70; same surgeon and anesthesia. Exclusion criteria: systemic disease

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
The samples using the seal envelop technique and double blind, both for patients and researchers are collected.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
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
EC/94/H/280

Health conditions studied

1

Description of health condition studied
laminectomy
ICD-10 code
M99
ICD-10 code description
vertebral column

Primary outcomes

1

Description
pain
Timepoint
1,4,8,12,24 h after intervention
Method of measurement
Visual Analogue Scale (VAS)

2

Description
Bleeding
Timepoint
During intervention in surgery time
Method of measurement
pad

3

Description
Nausea & Vomiting
Timepoint
After intervention in recovery
Method of measurement
checklist and VAS

4

Description
Blood pressure
Timepoint
During intervention in surgery time
Method of measurement
sphygmomanometer

5

Description
Hart rate
Timepoint
During intervention in surgery time
Method of measurement
Pulse oximeter

Secondary outcomes

1

Description
drug consumption
Timepoint
during 24 h after surgery
Method of measurement
Mg

2

Description
The first movement time
Timepoint
after intervention during discharge
Method of measurement
hrs

3

Description
duration of recovery room
Timepoint
After intervention
Method of measurement

hrs

4

Description
urinary retention
Timepoint
After intervention
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group 1: in propofol group 2-3 Mg/Kg propofol , o2 50%, N2o 50% was given.
Category
Treatment - Drugs

2

Description
Intervention group 2: in sevoflurane group 2-3 % Sevoflurane, o2 50%, N2o 50% was given
Category
Treatment - Drugs

3

Description
Intervention group 3: in sevoflurane plus propofol group 2-3 % Sevoflurane and 2-3 Mg/Kg propofol was given.
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 Blvd, Imam Khomeini Hospital, Ilam
City
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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 Blvd, Banganjab, Ilam
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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
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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