

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### The effect of Sevoflurane and Propofol on complications after laminectomy

#### Protocol summary

khani-a@medilam.ac.ir

##### 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.

##### 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

#### 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 84 3220 3150

###### Email address

##### 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**

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 Blvd, 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**

Shahid Beheshti Blvd, Imam Khomeini Hospital , Ilam

###### **City**

Ilam

###### **Postal code**

###### **Phone**

+98 84 3333 7259

###### **Fax**

###### **Email**

nimakhani@gmail.com; khani-a@medilam.ac.ir

###### **Web page address**

### **Person responsible for scientific 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**

Shahid Beheshti Blvd, Imam Khomeini Hospital , Ilam

###### **City**

Ilam

###### **Postal code**

###### **Phone**

+98 84 3333 7259

**Fax**

**Email**

nimakhani@gmail.com; khani-a@medilam.ac.ir

**Web page address**

+98 84 3333 7259

**Fax**

**Email**

nimakhani@gmail.com; khani-a@medilam.ac.ir

**Web page address**

## Person responsible for updating data

### 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**

Shahid Beheshti Blvd, Imam Khomeini Hospital, Ilam

**City**

Ilam

**Postal code**

**Phone**

## 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*