

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Comparison of two methods of general anesthesia using Isoflurane and Propofol for lumbar laminectomy surgery

#### Protocol summary

##### Summary

Objectives: The aim of this study is to compare the effect of maintenance anesthesia with propofol versus isoflurane on patients' blood loss and hemodynamic during simple laminectomy surgery. Design: clinical trial phase 3, unicentric study, 80 patients sample size, single blind, simple randomization. Setting and conduct: After assign inform consent, patients are allocated randomly into the propofol (P) and isoflurane (I). Anesthesiology specialist performs Induction and maintenance of anesthesia during surgery. Participants: patients, candidate for simple lumbar laminectomy surgery with ASA score  $\leq 2$ . Exclusion criteria are either sensitivity to propofol or isoflurane, a history of renal or coagulation disorders. Intervention: induction of anesthesiology and its maintenance using infusion of propofol (150 micro-grams per patient's weight (kg) per minutes) in P group, and isoflurane (1-1.5 maximum alveolar concentration (MAC)) in I group, through the whole duration of surgery. Outcome measures: primary outcome measures include Blood loss through Boezart criteria; volume of blood in suction bottle; estimated blood on gauzes; comparison of hematocrit and hemoglobin of blood obtained from surgical field; urinary output during surgery. Secondary outcome measures: mean arterial blood pressure; heart rate; duration of operation; need for blood transfusion.

#### General information

##### Acronym

ASA: American Society of Anesthesiology

##### IRCT registration information

IRCT registration number: **IRCT2015070723098N1**

Registration date: **2015-10-11, 1394/07/19**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-10-11, 1394/07/19

##### Registrant information

###### Name

Mohammadreza Shaghaghi

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4401 1753

###### Email address

mr-shaqaqi@student.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, AJA University of Medical Sciences

##### Expected recruitment start date

2015-09-01, 1394/06/10

##### Expected recruitment end date

2016-09-01, 1395/06/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of two methods of general anesthesia using Isoflurane and Propofol for lumbar laminectomy surgery

##### Public title

Comparison of two methods of intravenous and inhalation anesthesia for spinal disc surgery

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

inclusion criteria: laminectomy surgery for lumbar disc herniation; ASA score  $\leq$  2. exclusion criteria: Allergy to propofol; Allergy to isoflurane; Refuse patient; Coagulation disorders; History of renal disease

## **Age**

No age limit

## **Gender**

Both

## **Phase**

3

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **80**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

## **Blinding (investigator's opinion)**

Single blinded

## **Blinding description**

## **Placebo**

Not used

## **Assignment**

Parallel

## **Other design features**

simple randomization using pockets

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of AJA University of Medical Sciences

##### **Street address**

AJA University of Medical Sciences, Etemad Zadeh st, Fatemi st,

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2015-06-15, 1394/03/25

#### **Ethics committee reference number**

AJAUMS.REC.1394.15

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Hemorrhage

#### **ICD-10 code**

Y60.0

#### **ICD-10 code description**

During surgical operation

## **Primary outcomes**

### 1

#### **Description**

Blood on gauzes

#### **Timepoint**

End of surgery

#### **Method of measurement**

20 milliliter blood for each standard wet gauze. 50 milliliter for each long gauze.

### 2

#### **Description**

Quality of hemorrhage

#### **Timepoint**

End of surgery

#### **Method of measurement**

Boezart criteria

### 3

#### **Description**

Blood in suction bottle

#### **Timepoint**

End of surgery

#### **Method of measurement**

Volume of blood in suction bottle in milliliter

### 4

#### **Description**

Hematocrit of blood in surgical field

#### **Timepoint**

During surgery

#### **Method of measurement**

Laboratory measurement in percent

### 5

#### **Description**

Urine output

#### **Timepoint**

End of surgery

#### **Method of measurement**

Volume of liquid in urine bag in Milliliter

## **Secondary outcomes**

### 1

#### **Description**

Heart rate

#### **Timepoint**

15 minutes after anesthesia induction

#### **Method of measurement**

Electrocardiogram monitoring (beats per minute)

### 2

#### **Description**

Mean arterial blood pressure

### Timepoint

15 minutes after anesthesia induction

### Method of measurement

Automatic noninvasive blood pressure in mmHg

### 3

#### Description

Total duration of surgery

#### Timepoint

end of surgery

#### Method of measurement

Digital timer

### 4

#### Description

Blood transfusion

#### Timepoint

end of surgery

#### Method of measurement

Number of packed cells transfused

## Intervention groups

### 1

#### Description

continuous infusion of propofol (manufactured by Fresenius Kabi Austria GmbH) at dosage of 150 µ/kg/min is used for maintenance of anesthesia after induction. Infusion is performed for once during the whole operation time until the surgery is finished.

#### Category

Treatment - Drugs

### 2

#### Description

Inspiration of isoflurane (manufactured by Baxter corporation USA) at dosage of 1-1.5 % Maximum Alveolar Concentration for maintenance of anesthesia after induction. Inspiration of isoflurane is performed for once during the whole operation time until the end of surgery.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza hospital

##### Full name of responsible person

Ebrahim Hazrati

##### Street address

Etemad Zadeh st, Fatemi st,

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for research, AJA University of Medical Sciences

##### Full name of responsible person

Kamran Azma

##### Street address

Etemad zadeh st., Fatemi st.

##### City

Tehran

#### 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, AJA 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

Tehran University of Medical Sciences

##### Full name of responsible person

Mohammadreza Shaghaghi

##### Position

General practitioner

##### Other areas of specialty/work

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Poursina st, Keshavarz Blvd,

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##### Web page address

## Person responsible for scientific inquiries

#### Contact

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Anesthesiologist  
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## Person responsible for updating data

**Contact**  
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Tehran University of Medical Sciences  
**Full name of responsible person**  
Mohammadreza Shaghghi  
**Position**  
General practitioner

**Other areas of specialty/work**  
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**Fax**  
**Email**  
mr-shaqaqi@student.tums.ac.ir  
**Web page address**

## 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*