

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 ≤ 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)

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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

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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