

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of two anesthesia techniques, Isoflurane versus Propofol, on Intraocular Pressure (IOP) changes during prone position in laminectomy surgery

Protocol summary

Study aim

Comparison of two anesthesia techniques, Isoflurane versus Propofol, on intraocular pressure (IOP) changes during prone position in laminectomy surgery

Design

Phase 3, randomized clinical trial; Block randomization (blocks of size 4) using computer; Without blinding; with control group and parallel group design; sample size will be 64,.

Settings and conduct

This study will be conducted at the Amiralmomenin Medical Center of Rasht. After obtaining informed consent from patients, four groups of randomized blocks will be studied in two intervention and control groups. In one group, the following anesthetic drugs will be used: Premedication : fentanyl 3-5 µg/kg midazolam 1-2 mg Induction: propofol 2-2/5 mg/kg - cisatracurium 0/2mg/kg Maintenance: Isoflurane N2O In the other group: Premedication : fentanyl 3-5 µg/kg midazolam 1-2 mg Induction: propofol 2-2/5 mg/kg - cisatracurium 0/2mg/kg Maintenance: Propofol N2O

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidates for laminectomy Exclusion criteria: Eye disease history, Prohibition prone position, Prohibition of the use of toneupen, No use of any eye drops, No history of glaucoma and eye hypertension

Intervention groups

Intervention group: Anesthesia with isoflurane N2O
Control group: Anesthesia with propofol N2O

Main outcome variables

Intraocular pressure changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140310016917N7**

Registration date: **2018-11-30, 1397/09/09**

Registration timing: **prospective**

Last update: **2018-11-30, 1397/09/09**

Update count: **0**

Registration date

2018-11-30, 1397/09/09

Registrant information

Name

Ali Ashraf

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1321 0434

Email address

alishraf@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-01, 1397/09/10

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two anesthesia techniques, Isoflurane versus Propofol, on Intraocular Pressure (IOP) changes

during prone position in laminectomy surgery

Public title

Comparison of propofol and isoflurane on intraocular pressure changes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidates for laminectomy

Exclusion criteria:

Eye disease history Prohibition pron position Prohibition of the use of toneupen No use of any eye drops No history of glaucoma and eye hypertension

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 64

Randomization (investigator's opinion)

Randomized

Randomization description

Blocks of size 4 using statistical software

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Namjoo street

City

Rasht

Province

Guilan

Postal code

4193893345

Approval date

2018-10-06, 1397/07/14

Ethics committee reference number

IR.GUMS.REC.1397.246

Health conditions studied

1

Description of health condition studied

Candidates for laminectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Changes in intraocular pressure

Timepoint

In 5 turns:1. The patient supine position before induction of anesthesia (baseline phase) 2.Anesthesia (in the first supine position) 3.Anesthesia (in the first prone position) 4. End-stage surgery(in the second prone position) 5.Supine final step before awakening

Method of measurement

With toneupen device, Richter Model

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Anesthesia will be done with Isoflurane USP and N2O. In Premedication stage Remifentanyl 0.5 µg/kg and Midazolam 2 mg will be used intravenously. In Induction stage, Propofol 2 mg/kg and Cisatracurium 0/2mg/kg intravenously and in Maintenance stage, Isofluran USP 1.5% and N2O will be used By anesthesia machine. Propofol: Manufactured by DONGKOOK PHARM Company, South Korea, imported by TEDA Company. Isofeloran UPS: Manufactured by Bethehem Company, America, imported by TEDA Company.

Category

Treatment - Drugs

2

Description

Control group: Anesthesia will be done with propofol and N2O. In Premedication stage Remifentanyl 0.5 µg/kg and Midazolam 2 mg will be used intravenously. In Induction stage, Propofol 2 mg/kg and Cisatracurium 0/2mg/kg will be used intravenously and In Maintenance stage NO2 Inhaler through anesthesia machine and 2 mg/kg Propofol1% will be used. Propofol: Manufactured by DONGKOOK PHARM Company, South Korea, imported by TEDA Company. Isofeloran UPS: Manufactured by Bethehem Company, America, imported by TEDA Company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmoemenin hospital

Full name of responsible person

Ali Ashraf

Street address

Dr. Heshmati Square., Shahrivar St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Shadman Nemati

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Shahid Siyadati street, Namjoo street

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Grant name

Namjoo Street, Shahid Siadati, Rasht

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rasht University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Ali Ashraf

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available