Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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- -cisatracuriom 0/2mg/kg Maintenance: Isofluran N2O In the other group: Premedication : fentanyl 3-5 µg/kg midazolam 1-2 mg Induction:propofol 2-2/5 mg/kg- -cisatracuriom 0/2mg/kg Maintenance: Propofol N2O

Participants/Inclusion and 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

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
aliashraf@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 Cisatracuriom 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 Cisatracuriom 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.

City
Rasht

Province
Guilan

Postal code
41937-13194

Phone
+98 13 3323 6886

Fax
+98 13 3323 6886

Email
crdu.Poursina@gums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Shadman Nemati

Street address
Shahid Siyadati street, Namjoo street

City
Rasht

Province
Guilan

Postal code
41937-13194

Phone
+98 13 3333 6394

Fax
+98 13 3333 6395

Email
research@gums.ac.ir

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

Street address
Prastar street

City
Rasht

Province
Guilan

Postal code
41937-13194

Phone
+98 13 3332 2250

Email
aliashraf@gums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Ali Ashraf

Position
Associate professor

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Phone
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Email
aliashraf@gums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences

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+98 13 3332 2250

Email
aliashraf@gums.ac.ir

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