

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of the Effect of Propofol and Sevoflurane Anesthesia on Intraocular Pressure in Patients Undergoing Cataract Surgery.

Protocol summary

Study aim

Comparison of the Effect of Propofol and Sevoflurane Anesthesia on Intraocular Pressure in Patients Undergoing Cataract Surgery.

Design

Double blinded randomized clinical trial

Settings and conduct

After doing the blinding study so that the patient and assessor, who is a resident ophthalmologist and measures and records intraocular pressure, do not know the type of study groups. Patients are divided into two groups in the operating room of Khalili Hospital of Shiraz, in the first intervention group, anesthesia will be maintained with propofol 100 mg / kg / min. In the second intervention group, anesthesia will be maintained with a maintenance dose of sevoflurane (3.3% MAC).

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients candidate for cataract surgery, Age 30-70 years, Class (ASA) I, II. Exclusion Criteria: allergies or adverse effects to any of the studied drugs, Blood pressure, Congestive heart failure, Difficult airway management or failure to pass the LMA, Brain Tumor, IOP history, Glaucoma, Other eye diseases, Previous eye surgery.

Intervention groups

Intervention group: In the first intervention group, anesthesia will be maintained with propofol 100 mg / kg / min with oxygen and nitrous oxide of 0.5% and maintaining capnography between 30-35 mm Hg. In the second intervention group, anesthesia will be maintained with a maintenance dose of sevoflurane (3.3% MAC) and 0.5% oxygen and nitrous oxide and capnography 30-35 mm Hg.

Main outcome variables

Intraocular pressure, Blood pressure.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N97**

Registration date: **2020-01-29, 1398/11/09**

Registration timing: **prospective**

Last update: **2020-01-29, 1398/11/09**

Update count: **0**

Registration date

2020-01-29, 1398/11/09

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3647 4270

Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-24, 1398/12/05

Expected recruitment end date

2020-04-24, 1399/02/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Propofol and Sevoflurane Anesthesia on Intraocular Pressure in Patients Undergoing Cataract Surgery.

Public title

Comparison the Effect of Propofol and Sevoflurane Anesthesia on Intraocular Pressure in Patients Undergoing Cataract Surgery.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients candidate for cataract surgery Age 30-70 years Class (ASA) I, II

Exclusion criteria:

Known allergies or adverse effects to any of the studied drugs Blood pressure Congestive heart failure Difficult airway management or failure to pass the LMA Brain Tumor IOP history Glaucoma Other eye diseases Previous eye surgery

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

At Randomization.org, I receive two sets of 72 code from the table extracted from the site and share among the 144 study participants. (72 patients receiving will be assigned to the Sevoflurane group and the rest to the Propofol group) who will eventually be divided into the S and P groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and assessor, who is a resident ophthalmologist and measures and records intraocular pressure, do not know the type of study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical

Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2019-12-14, 1398/09/23

Ethics committee reference number

IR.SUMS.MED.REC.1398.510

Health conditions studied

1

Description of health condition studied

Cataract Surgery

ICD-10 code

H25

ICD-10 code description

Age-related cataract

Primary outcomes

1

Description

Intraocular pressure

Timepoint

Baseline(before premedication), Before induction of anesthesia, 1min after induction of anesthesia, 1min after muscle relaxation, Immediately after LMA insertion, 5 min after LMA insertion, Immediately before extubation of the LMA, After extubation of the LMA

Method of measurement

Intraocular pressure monitor (Tonometer)

Secondary outcomes

1

Description

Blood pressure

Timepoint

From the beginning of the surgery every 5 minutes to 45 minutes (end of the operation)

Method of measurement

Blood pressure monitor

Intervention groups

1

Description

Intervention group: In the first intervention group, anesthesia will be maintained with propofol 100 mg / kg

/min with oxygen and nitrous oxide of 0.5% and maintaining capnography between 30-35 mm Hg.

Category

Prevention

2

Description

Intervention group: In the second intervention group, anesthesia will be maintained with a maintenance dose of sevoflurane (3.3% MAC) and 0.5% oxygen and nitrous oxide and capnography 30-35 mm Hg.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili Hospital

Full name of responsible person

Mohammad Amin Etezadi

Street address

Khalili Hospital, Khalili Street

City

Shiraz

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Postal code

7134814336

Phone

+98 71 3627 1671

Email

amin.etezadi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghasemi

Street address

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Amin Etezadi

Position

Anesthesiology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Zinabosadat Fatahi

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Farzaneh Masihi

Position
BS in anesthesia/English Consultant

Latest degree
Master

Other areas of specialty/work
Anesthesiology

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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

Its against our policies.

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