

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The comparison intraocular pressure changes in patients that candidate for cataract surgery with local anesthesia and general anesthesia with laryngeal mask airway and variety of laryngoscopy

Protocol summary

Study aim

Comparison of intraocular pressure changes in patients undergoing cataract surgery under local anesthesia and general anesthesia with laryngeal mask airway and types of laryngoscopy. Comparison of hemodynamic changes (systolic, diastolic and mean arterial blood pressure) in patients undergoing cataract surgery under local anesthesia and general anesthesia with laryngeal mask airway and laryngoscopy types.

Design

A clinical trial with a control group, with 5 parallel group, double-blind, randomized

Settings and conduct

The study of hemodynamic stress in 5 groups patients in operating room of Moradi Hospital in Rafsanjan was performed. Patient and data analyst did not know the effect of methods on hemodynamics.

Participants/Inclusion and exclusion criteria

Patients referring to operating room of Moradi hospital in Rafsanjan for elective cataract surgery in 2018-19

Intervention groups

Intubation with Macintosh Direct Laryngoscope with Blade 3 Intubation with McCoy Direct Laryngoscope with Blade 3 Intuition with glidescope with blade 3 Laryngeal mask airway embedded in the classical way

Main outcome variables

Increased blood pressure; increased intraocular pressure

General information

Reason for update

Acronym

LMA, ASA

IRCT registration information

IRCT registration number: **IRCT20190112042327N1**

Registration date: **2019-01-30, 1397/11/10**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-30, 1397/11/10**

Update count: **0**

Registration date

2019-01-30, 1397/11/10

Registrant information

Name

Asma Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 4321 1130

Email address

medical13@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison intraocular pressure changes in patients that candidate for cataract surgery with local anesthesia and general anesthesia with laryngeal mask airway and variety of laryngoscopy

Public title

The comparison intraocular pressure changes in patients that candidate for cataract surgery with local anesthesia

and general anesthesia with laryngeal mask airway and variety of laryngoscopy	Ethics committee of Rafsanjan University of Medical Sciences
Purpose	Street address
Prevention	Koye Asatid., Sarallah Ave., Emam Blvd., Rafsanjan Town
Inclusion/Exclusion criteria	City
Inclusion criteria:	Rafsanjan
40 to 80 years old Candidate of Elective Cataract Surgery by Phacoemulsification ASA Class 1 and 2	Province
Exclusion criteria:	Kerman
Cardiovascular, respiratory, neovascular, coagulopathy disease High risk for aspiration History of difficult Intubation Likely probability of difficult intubation in clinical examination Aspiration and vomiting during induction of anesthesia Cardiac arrest during induction of anesthesia, laryngoscopy and surgery Use of sedative over the past 24 hours	Postal code
	7716614697
	Approval date
	2017-12-26, 1396/10/05
	Ethics committee reference number
	IR.RUMS.REC.1396. 149
Age	Health conditions studied
From 40 years old to 80 years old	<u>1</u>
Gender	Description of health condition studied
Both	Changes in intraocular pressure and hemodynamics
Phase	ICD-10 code
N/A	ICD-10 code description
Groups that have been masked	Primary outcomes
- Participant - Outcome assessor	<u>1</u>
Sample size	Description
Target sample size: 170	hemodynamic Changes
Actual sample size reached: 170	Timepoint
Randomization (investigator's opinion)	Before the intervention, immediately after the intervention, five minutes after the intervention
Randomized	Method of measurement
Randomization description	Arterial pressure is measured through an automatic pressure gauge (SAADAT model) and heart rate (via ECG).
In order to randomize the study, 170 cards were prepared in 5 groups of 34 groups A, B, C, D, E and each patient randomly selected one of the cards and entered the corresponding group.	Secondary outcomes
Blinding (investigator's opinion)	<u>1</u>
Double blinded	Description
Blinding description	Intraocular pressure changes
At first, for the participants, 5 groups were explained and after consent, Patients were included in the study, while they were randomly selected and the outcome was not known. The person who carried out the outcome evaluation used different methods and its effect on the outcome was not known.	Timepoint
Placebo	Before the intervention, immediately after the intervention, five minutes after the intervention
Not used	Method of measurement
Assignment	Tonopon Tonometer
Parallel	Intervention groups
Other design features	<u>1</u>
Secondary Ids	Description
empty	Intervention group: Intubation is performed with a Macintosh direct laryngoscope with blade 3.
Ethics committees	Category
<u>1</u>	Prevention
Ethics committee	
Name of ethics committee	

2

Description

Intervention group: Intubation is performed with the McCoy Direct Laryngoscope with Blade 3.

Category

Prevention

3

Description

Intervention group: Intubation is performed with a glideoscope with a blade 3.

Category

Prevention

4

Description

Intervention group: The laryngeal mask AIRWAY is embedded in a classic way.

Category

Prevention

5

Description

Control group: Local anesthetic with 0.5% tetracaine drops

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Moradi hospital

Full name of responsible person

Asma Amiri

Street address

Shohada Ave., Rafsanjan Town

City

Rafsanjan

Province

Kerman

Postal code

7861755763

Phone

+98 34 3325 6563

Email

asma.amirid@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Reza motamedi

Street address

Ali ebn Abitaleb Hospital, Imam Ali Blvd, Rafsanjan City

City

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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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Asma Amiri

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

there is no more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable