

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of lidocaine gel and lubricant gel on hemodynamic symptoms and withdrawal reactions with two methods of laryngeal mask and endotracheal tube in patients undergoing cataract surgery

Protocol summary

Study aim

Comparison of lidocaine gel and lubricant gel methods on hemodynamic symptoms and withdrawal reactions under anesthesia with laryngeal mask and endotracheal tube in patients undergoing cataract surgery

Design

This study will be a randomized clinical trial with parallel groups on 66 patients referred to Peymaniyeh Motahhari Hospital in Jahrom who undergo cataract surgery. Patients participating in the study will be divided into two groups by tossing coins.

Settings and conduct

Patients referred to Motahhari Hospital in Jahrom who will undergo cataract surgery will be included in the study. Patients participating in the study will be divided into two groups by endotracheal intubation and laryngeal mask by throwing coins.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients referred to Motahhari Hospital in Jahrom who underwent cataract surgery and expressed their consent to participate in the study. Non-entry conditions: includes patients who do not have hemodynamic stability and suffer from acute and chronic pain.

Intervention groups

Intervention group 1: In order to establish the airway in this group, endotracheal intubation was used. The members of this group were intubated with three methods: lidocaine gel, lubricant gel and normal sign. Intervention group 2: To establish the airway in this group, laryngeal mask was used. The members of this group tried to maintain the airway with three methods: lidocaine gel, lubricant gel and normal sign.

Main outcome variables

Hemodynamic symptoms, sore throat and cough, agitation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210415050976N6**

Registration date: **2021-08-06, 1400/05/15**

Registration timing: **prospective**

Last update: **2021-08-06, 1400/05/15**

Update count: **0**

Registration date

2021-08-06, 1400/05/15

Registrant information

Name

navid kalani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5433 6085

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-02, 1400/07/10

Expected recruitment end date

2021-12-31, 1400/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of lidocaine gel and lubricant gel on hemodynamic symptoms and withdrawal reactions with two methods of laryngeal mask and endotracheal tube in patients undergoing cataract surgery

Public title

Comparison of lidocaine gel and lubricant gel on hemodynamic symptoms and withdrawal reactions with two methods of laryngeal mask and endotracheal tube in patients undergoing cataract surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Hemodynamic stability ASA (Class 1 and 2 were considered as inclusion criteria)

Exclusion criteria:

History of cardiovascular disease Shortness of breath
Glaucoma

Age

From **25 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **99**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization method is used. With the help of the online site (www.sealedenvelope.com/simple-randomiser/v1/lists) randomization, 4 blocks of 14 are created. In each randomly assigned block, 14 patients are assigned to the endotracheal intubation group and 14 patients to the laryngeal mask group.

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 Jahrom University of Medical Sciences

Street address

Jahrom, Shahid Motahari Boulevard, Jahrom University of Medical Sciences, Vice Chancellor for Research

City

Jahrom

Province

Fars

Postal code

7167758256

Approval date

2021-03-03, 1399/12/13

Ethics committee reference number

IR.JUMS.REC.1399.147

Health conditions studied

1

Description of health condition studied

Cataract

ICD-10 code

E08.36

ICD-10 code description

Diabetes mellitus due to underlying condition with diabetic cataract

Primary outcomes

1

Description

Hemodynamic symptoms

Timepoint

It will be measured before, immediately, 5, 15 and 30 minutes after anesthesia as well as during recovery.

Method of measurement

monitoring

2

Description

Agitation

Timepoint

Immediately after transfer to recovery, 1, 6, 12 and 24 hours after surgery in the ophthalmology department

Method of measurement

The measure of restlessness

3

Description

Sore throat

Timepoint

Immediately after transfer to recovery, 1, 6, 12 and 24 hours after surgery in the ophthalmology department

Method of measurement

VAS criteria

4

Description

Cough

Timepoint

Immediately after transfer to recovery, 1, 6, 12 and 24 hours after surgery in the ophthalmology department

Method of measurement

Based on having or not having a cough

Secondary outcomes

1

Description

Nausea and vomiting

Timepoint

Immediately after transfer to recovery, 1, 6, 12 and 24 hours after surgery in the ophthalmology department

Method of measurement

Vomiting nausea questionnaire

2

Description

chills

Timepoint

Immediately after transfer to recovery, 1, 6, 12 and 24 hours after surgery in the ophthalmology department

Method of measurement

Shivering Questionnaire

Intervention groups

1

Description

Intervention group 1: In order to establish the airway in this group, endotracheal intubation was used. The individuals of this group were intubated with three methods: lidocaine gel, lubricant gel and normal sign. From each of the lidocaine, lubricant or normal saline gels, 3 cc is drawn and poured separately on the cuff part of the tube.

Category

Treatment - Devices

2

Description

Intervention group 2: To establish the airway in this group, laryngeal mask was used. The members of this group tried to maintain the airway with three methods: lidocaine gel, lubricant gel and normal sign. From each of the lidocaine, lubricant or normal saline gels, 3 cc is drawn and poured separately on the cuff part of the tube.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahhari Hospital of Jahrom city

Full name of responsible person

Navid Kalani

Street address

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71677251542

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Kavose Solh Joo

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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

Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

Navid Kalani

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

Contact

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available