

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of dual use of lubricant gel & lidocaine gel and normal saline during lining the airway)LMA(on hemodynamic symptoms and anesthesia withdrawal reactions in cataract surgery

Protocol summary

Study aim

Comparison of dual use of lubricant gel & lidocaine gel and normal saline during lining the airway)LMA(on hemodynamic symptoms and anesthesia withdrawal reactions in cataract surgery

Design

This study was performed by randomized clinical trial with control group with factorial groups on 180 patients with cataracts referred to Motahhari Hospital in Jahrom city. Patients participating in the study were divided into three groups by throwing dice: 1) lubricant gel 2) lidocaine gel 3) normal saline.

Settings and conduct

This study of randomized clinical trial on patients undergoing cataract surgery referred to Motahhari Hospital in Jahrom in 1397 was studied. Patients were divided into three groups if they had the criteria to enter the study by baldness. Symptoms of hemodynamics and anesthesia reactions were examined in three group

Participants/Inclusion and exclusion criteria

Entry criteria: All patients referred to Ustad Motahhari Hospital in Jahrom city who undergo cataract surgery with general anesthesia with laryngeal mask. exclusion criteria: Expressing dissatisfaction with participating in the study and not having the criteria to enter the study

Intervention groups

Intervention Group 1: Lubricant gel was used while applying the laryngeal mask. Intervention Group 2: Lidocaine gel was used while applying the laryngeal mask. Control group: Normal saline was used while applying the laryngeal mask.

Main outcome variables

Symptoms of hemodynamics, anesthesia reactions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130926014779N3**
Registration date: **2020-05-26, 1399/03/06**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-26, 1399/03/06**

Update count: **0**

Registration date

2020-05-26, 1399/03/06

Registrant information

Name

Navid Kalani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5426 4192

Email address

k.navid@jums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-31, 1398/10/10

Expected recruitment end date

2020-07-10, 1399/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of dual use of lubricant gel & lidocaine gel

and normal saline during lining the airway)LMA(on hemodynamic symptoms and anesthesia withdrawal reactions in cataract surgery

2019-01-16, 1397/10/26

Ethics committee reference number
IR.JUMS.REC.1397.112

Public title

omparison of dual use of lubricant gel & lidocaine gel and normal saline during lining the airway (LMA)

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Interest in participating in the study Hemodynamic stability

Exclusion criteria:

People who need medication or action other than routine care during surgery to relieve complications and reduce pain. Smoking and drug use Chronic and cancerous pains

Age

No age limit

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients in the study were divided into three groups by throwing dice.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

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

School of medicine, Motahhari Blvd, Jahrom

City

jahrom

Province

Fars

Postal code

7165515551

Approval date

Health conditions studied

1

Description of health condition studied

Cataract

ICD-10 code

H25

ICD-10 code description

Age-related cataract

Primary outcomes

1

Description

Hemodynamic changes (heart rate, systolic and diastolic blood pressure)

Timepoint

Immediately before the operation, immediately after the Induction, 5 minutes after the operation, 15 minutes after the operation and 30 minutes after the operation, and as soon as you enter recovery.

Method of measurement

Using the device to measure vital signs

2

Description

Cough episode

Timepoint

During patient extubation, 6 hours after surgery, recovery

Method of measurement

questionnaire

3

Description

Sore throat

Timepoint

During patient extubation, 6 hours after surgery, recovery

Method of measurement

Visual scale of pain

Secondary outcomes

1

Description

Nausea - vomiting

Timepoint

During patient extubation, 6 hours after surgery, recovery

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention Group 2: Lidocaine gel was used when applying the laryngeal mask.

Category

Treatment - Devices

2

Description

Intervention Group 1: Lubricant gel was used when applying the laryngeal mask.

Category

Treatment - Devices

3

Description

Control group: Normal sine was used when applying the laryngeal mask.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahhari Hospital of Jahrom

Full name of responsible person

Seyed Hamed Hojjati

Street address

Vice chancellor for research, Jahrom University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Solh Ju Kavos

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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

نوید کلانی

Position

Research employee

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Position

Research employee

Latest degree

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Other areas of specialty/work

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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

No - There is not 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

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