Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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+98 71 5426 4192

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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

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
2019-01-16, 1397/10/26
Ethics committee reference number
IR.JUMS.REC.1397.112

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
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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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Vice chancellor for research, Jahrom University of Medical Sciences, Motahhari Blvd, Jahrom
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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
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Master
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Anesthesiology
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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
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