

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the use of lubricant gel and lidocaine gel during the placement of LAM (Laryngeal Mask Airway) on hemodynamics and symptoms of withdrawal reactions in the patients out of anesthesia in 501 Army hospital

Protocol summary

Summary

(1) Objective: To assess the use of lubricant gel and lidocaine gel during placement of laryngeal mask on Hemodynamic changes and emergence reactions of anesthesia in patients (2) Design: This study is a clinical double blind trial and will be done in all 60 -20 years old patients with ASA class I who admitted to Army hospital for varicocele surgery. (3) how to do: All patients were anesthetized with a similar general anesthesia(5 ml per kg liquid then injection of 4 micro grams per kg of fentanyl and 0.5 mg per kg atracurium and 5 mg for every kg of sodium thiopental). And maintenance of anesthesia was done by mask and using nitrous oxide and 50% oxygen and 5 mg per kg per hour propofol. (4)Inclusion criteria: Male patients, aged 20 to 60 years; ASA I; varicocele surgery with general anesthesia; completing consciously the consent form to participate in research projects. Exclusion criteria: Over 60 years old; ASA class II ,III and IV; a history of sore throat and lung disease; drug addiction; any heart disease - liver -Kidney; allergic to any medicine. (5) Interventions: use of lidocaine gel during insertion of laryngeal mask (6) The main outcome variables: lidocaine gel during insertion of laryngeal mask can be affected in intraoperative hemodynamic changes and frequency of emergence reactions from anesthesia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011716906N2**

Registration date: **2016-05-11, 1395/02/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-11, 1395/02/22

Registrant information

Name

Behzad Kazemi Haki

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 914 938 0765

Email address

behzad_empt@yahoo.com

Recruitment status

Recruitment complete

Funding source

Army University of Medical Science

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2013-06-23, 1392/04/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the use of lubricant gel and lidocaine gel during the placement of LAM (Laryngeal Mask Airway) on hemodynamics and symptoms of withdrawal reactions in the patients out of anesthesia in 501 Army hospital

Public title

Comparison of the use of lubricant gel and lidocaine gel in the placement of laryngeal mask on Hemodynamic and reactions in the patients out of anesthesia in 501 Army hospital

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Male patients, aged 20 to 60 years; ASA I; varicocele with general anesthesia; completing consciously the consent form to participate in research projects. Exclusion criteria: Over 60 years old; ASA class II ,III and IV; a history of sore throat and lung disease; drug addiction; any heart disease - liver -Kidney; allergic to any medicine.

Age

From **20 years** old to **60 years** old

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Army University of Medical Sciences

Street address

Martyr Etemadzadeh Street, West Fatemi Avenue

City

Tehran

Postal code

1411718541

Approval date

2013-01-09, 1391/10/20

Ethics committee reference number

9111

Health conditions studied

1

Description of health condition studied

Varicocele

ICD-10 code

I86.1

ICD-10 code description

Varicocele

Primary outcomes

1

Description

blood pressure

Timepoint

evry 5 minutes, before, in during and after itervention

Method of measurement

By using blood pressure measuring equipment

2

Description

heart beat

Timepoint

evry 2 minutes. before, in during and after intervention

Method of measurement

By using ECG monitoring

3

Description

weight

Timepoint

after intervention

Method of measurement

Based on individual weighing with standard scales

4

Description

nauesa and vomiting

Timepoint

before, in during and after intervention

Method of measurement

View raising or attempting to raise involuntary stomach contents

5

Description

Sore throat

Timepoint

befor and after intervention

Method of measurement

ask the patient

6

Description

Cough

Timepoint
before and after intervention
Method of measurement
observation

7

Description
age
Timepoint
before intervention
Method of measurement
By date of birth (birth certificate)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group The use of lidocaine gel during insertion of laryngeal mask the extent one inch or 2.5 cm
Category
Treatment - Drugs

2

Description
control group The use of lubricant gel during insertion of laryngeal mask the extent one inch or 2.5 cm
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital of Army university of medical sciences
Full name of responsible person
Mohammad Reza Rafiee
Street address
Martyr Etemadzadeh Street, West Fatemi Avenue
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Army University of Medical Sciences
Full name of responsible person
Banafshe Dormanesh
Street address

Martyr Etemadzadeh Street, West Fatemi Avenue -
Deputy of research and technology

City
Tehran

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Army University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Urmia University of Medical Sciences
Full name of responsible person
Behzad Kazemi Haki
Position
Inventor and Researcher
Other areas of specialty/work
Street address
Department of Anesthesia, Operating Room Ward of Imam Khomeini hospital of Mahabad
City
Mahabad
Postal code
591375481
Phone
+98 44 4222 5779
Fax
Email
behzad_emt@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Army University of Medical Sciences
Full name of responsible person
Mohammad Reza Rafiee
Position
associated professor of anesthesia
Other areas of specialty/work
Street address
martyr Etemadzadeh Street, West Fatemi Avenue,
Army University of Medical Sciences

City
Tehran
Postal code
1411718541
Phone
+98 21 8595 2959
Fax
+98 21 8833 7909
Email
info@ajaums.ac.ir
Web page address

Mahabad
Postal code
591375481
Phone
+98 44 4222 5779
Fax
Email
behzad_emt@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Urmia University of Medical Sciences
Full name of responsible person
Behzad Kazemi Haki
Position
Inventor and Researcher
Other areas of specialty/work
Street address
Department of anesthesia, Operation room ward,
Mahabad Imam Khomeini hospital
City

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty