# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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 varicocelectomy 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; varicocelectomy 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

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**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; varicocelectomy 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**
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## Person responsible for scientific inquiries

**Contact**
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Mohammad Reza Rafiee
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## Person responsible for updating data

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## 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*