

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

A comparison between intravenous and topical spray of lidocaine on hemodynamic changes and discomfort feeling in throat/larynge following to LMA insertion in general anesthesia

Protocol summary

Study aim

A comparison between intravenous and topical spray of lidocaine on hemodynamic changes and discomfort feeling in throat/larynge following to LMA insertion in general anesthesia

Design

A randomized clinical trial without control group, with parallel groups, phase 3. without blindness that, 120 patients randomly divided into two groups of 60 subjects with block sizes of 4 and 6.

Settings and conduct

The population of this study was aged 18-65 years old who referred to Ayatollah Rouhani Hospital in Babol. randomly divided into two Intervention groups with block sizes of 4 and 6.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 18-65 years old, ASA class I-II
Exclusion Criteria: History of laryngeal or tracheal surgery, History of allergic reaction, Smoking, Addiction

Intervention groups

Intervention Group 1: Three minutes before LMA placement, 1.5 mg / kg intravenous lidocaine (Aborihan Comany) and normal saline (Samen Company) spray are given at the bottom of the throat. Intervention Group2: Three minutes before LMA placement, the patient's pharynx is smeared with 2% lidocaine spray (Kharazmi Company) (0.1ml / puff) and the entire LMA cuff is soaked with lidocaine gel 2% (Sina daro Company) before placement.

Main outcome variables

Blood Pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141121020020N5**

Registration date: **2020-06-06, 1399/03/17**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-06, 1399/03/17**

Update count: **0**

Registration date

2020-06-06, 1399/03/17

Registrant information

Name

Shahram Seyfi

Name of organization / entity

Babol University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 11 3223 8284

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sh.seyfi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-18, 1398/11/29

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between intravenous and topical spray of lidocaine on hemodynamic changes and discomfort

feeling in throat/larynge following to LMA insertion in general anesthesia

Public title

A comparison between intravenous and topical spray of lidocaine on discomfort feeling in throat/larynge in general anesthesia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

18-65 years old ASA class I-II

Exclusion criteria:

History of laryngeal or tracheal surgery, History of allergic reaction Smoking Addiction

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients into two intervention groups Patients are randomly divided into two groups A and B with a table of random numbers (a random number table is a collection of numbers that are generated without a specific pattern or order and completely randomized, then samples are randomly selected by Randomizer software

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 Babol University Of Medical Sciences

Street address

Daneshgah Square, Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

47176-41367

Approval date

2020-02-18, 1398/11/29

Ethics committee reference number

IR.MUBABOL.HRI.REC.1398.343

Health conditions studied

1

Description of health condition studied

General Anesthesia

ICD-10 code

T88.5

ICD-10 code description

Other complications of anesthesia

Primary outcomes

1

Description

Blood Pressure

Timepoint

Before and during intervention and after recovery time. 1, 3, 5, 10, 15 min after drug injection and 3, 5, 15, 30 min after recovery

Method of measurement

Blood pressure manometer by mmHg

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Three minutes before LMA placement, 1.5 mg / kg intravenous lidocaine (Aborihan Comany) and normal saline (Samen Company) spray are given at the bottom of the throat

Category

Prevention

2

Description

Intervention group: Three minutes before LMA placement, the patient's pharynx is smeared with 2% lidocaine spray (Kharazmi Company) (0.1ml / puff) and the entire LMA cuff is soaked with lidocaine gel 2% (Sina daro Company) before placement

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital

Full name of responsible person

Shahram Seyfi

Street address

Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

Street address

Daneshgah Square, Ganjafrooz Avenue

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Shahram Seyfi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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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 still no plan for its publish

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

No - There is not 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