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

Email address
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

City
Babol

Province
Mazandaran

Postal code
47176-41367

Phone
+98 11 3233 5308

Email
ficu_ss@yahoo.com

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

City
Babol

Province
Mazandaran

Postal code
47176-41367

Phone
+98 11 3219 7667

Email
rezaghadimi@yahoo.com

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

Street address
Ayatollah Rouhani Hospital, Daneshgah Square, Ganjafrooz Avenue

City
Babol

Province
Mazandaran

Postal code
47176-41367

Phone
009811322335308

Email
ficu_ss@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Shahram Seyfi

Position
Assistant Professor

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Street address
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Postal code
47176-41367

Phone
009811322335308

Email
ficu_ss@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Shahram Seyfi

Position
Assistant Professor
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Anesthesiology
Street address
Ayatollah Rouhani Hospital, Daneshgah Square, Ganjafrooz Avenue
City
Babol
Province
Mazandaran
Postal code
47176-41367
Phone
009811322338305
Email
ficu_ss@yahoo.com

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