

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Anesthesia for the Child with Mild Upper Respiratory Tract Infection: Comparison of intravenous vs. topical lidocaine

Protocol summary

Summary

Objectives: To evaluate the preventive effect of topical versus intravenous lidocaine on postoperative cough in children with mild upper respiratory tract infection (URI) anesthetized with laryngeal mask airway (LMA) Inclusion: Children with mild URI aged 1-6 y undergoing anesthesia for ophthalmic examination. Exclusion: Anesthesia lasting more than an hour or requiring extra drugs Randomization: patients were randomized to receive intravenous vs. topical (on LMA) lidocaine while same volume of normal saline or lubricating gel was applied as placebo. Method: 130 patients anesthetized by incremental doses of sevoflurane and received intravenous atropine (0.01 mg/kg). One group received intravenous lidocaine (1.5 mg/kg) and topical placebo on LMA. The other group received intravenous placebo and topical lidocaine. LMA was inserted in deep anesthesia. Patients received sevoflurane (3%) with N2O and O2 (50%) (While on spontaneous respiration) for maintenance and LMA removed at the end of examination in deep state. Measurements: Cough was assessed as primary outcome while apnea, desaturation, laryngospasm, bronchospasm and readmission (one day postoperative) evaluated as secondary outcomes. Outcomes were assessed during induction, maintenance, emergence and recovery (albeit readmission was recorded one day postoperatively).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812083436N1**

Registration date: **2012-08-07, 1391/05/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-07, 1391/05/17

Registrant information

Name

Babak Gharaei

Name of organization / entity

Labbafijezad Hospital, Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2254 9029

Email address

b.gharaei@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2011-12-12, 1390/09/21

Expected recruitment end date

2012-05-01, 1391/02/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Anesthesia for the Child with Mild Upper Respiratory Tract Infection: Comparison of intravenous vs. topical lidocaine

Public title

Anesthesia for the Child with Mild Upper Respiratory Tract Infection: Comparison of intravenous vs. topical lidocaine

Purpose

Prevention

-400/6874

Inclusion/Exclusion criteria

Inclusion criteria: All pediatric patients between 1-6 y-old whose parents mentioned mild URI symptoms (nasal discharge or congestion, cough, sneeze) started within last two weeks No evidence of bacterial infection (axillary temperature more than 38, ill appearance evaluated by anesthesiologist in charge, purulent discharge or sputum) No evidence of lower respiratory infection (crackle or wheeze) No evidence of medical condition (respiratory, cardiac or neurologic) Patients candidate for anesthesia to receive full ophthalmologic examination. These procedures were necessary to perform and further delay would have deleterious consequences. Exclusion criteria: Those with a probable difficult airway Hypersensitivity to drugs Patients who received hydrocortisone, dexamethasone or extra atropine and vasopressor Those who required muscle relaxant due to unpredicted surgery plan change or procedures lasting more than an hour

Age

From **1 year** old to **6 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Randomized

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

Shahid Beheshti University of Medical Sciences/Ethics Committee

Street address

Chamran- Evin- side to Taleghani Hospital

City

Tehran

Postal code

Approval date

2011-12-11, 1390/09/20

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Acute nasopharyngitis

ICD-10 code

J00

ICD-10 code description

Coryza (acute)Nasal catarrh, acute Nasopharyngitis

Primary outcomes

1

Description

Cough

Timepoint

Induction, maintenance, emergence, recovery

Method of measurement

observation and questionnaire

Secondary outcomes

1

Description

Desaturation (SPO2 less than 90% for more than one minute)

Timepoint

induction, maintenace, emergence and recovery (continuous)

Method of measurement

pulsoximetry

2

Description

Apnea (no airflow for more than 10 seconds)

Timepoint

induction, maintenace, emergence and recovery

Method of measurement

Observation

3

Description

laryngospasm (inspiratory stridor)

Timepoint

induction, maintenance, emergence and recovery (every 5 minutes)

Method of measurement

observation and questionnaire

4

Description

Bronchospasm (inspiratory or expiratory wheeze)

Timepoint

induction, maintenance, emergence and recovery (every

5 minutes)
Method of measurement
observation and questionnaire

5

Description
vomiting
Timepoint
induction, maintenance, emergence and recovery (every 5 minutes)
Method of measurement
observation and questionnaire

6

Description
Cardiac event (any medication for cardiac support)
Timepoint
induction, maintenance, emergence and recovery
Method of measurement
questionnaire

Intervention groups

1

Description
intravenous lidocaine (1.5 mg/kg)
Category
Prevention

2

Description
intravenous normal saline
Category
Placebo

3

Description
Topical lidocaine (2% lidocaine) on laryngeal mask airway
Category
Prevention

4

Description
Topical lubrication gel on laryngeal mask airway
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Labbafinejad Hospital
Full name of responsible person
Babak Gharaei

Street address
Boostan the 9th
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Homayoun Aghamohammadi
Street address
Labbafinejad Hospital, 9th Boostan, Pasdaran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Babak Gharaei
Position
Assistant professor
Other areas of specialty/work
Street address
Labbafinejad Hospital, 9th Boostan ,Pasdaran
City
Tehran
Postal code
Phone
+98 21 2254 9029
Fax
Email
babakgharaei@gmail.combabakgharaei@yahoo.com
Web page address

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Babak Gharaei

Position

Assistant Professor

Other areas of specialty/work

Street address

Labbafinejad Hospital, 9th Boostan, Pasdaran

City

Tehran

Postal code

Phone

+98 21 2254 9029

Fax

Email

babakgharaei@gmail.combabakgharaei@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Babak Gharaei

Position

Assistant professor

Other areas of specialty/work

Street address

Labbafinejad Hospital, 9th Boostan, Pasdaran

City

Tehran

Postal code

Phone

+98 21 2254 9029

Fax

Email

Web page address

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