

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The comparative Evaluation of Efficacy of intravenous lidocaine 2% and propofol in preventing laryngospasm and complications after tonsilectomy

Protocol summary

Study aim

The comparative Evaluation of Efficacy of intravenous lidocaine 2% and propofol in preventing laryngospasm and complications after tonsilectomy

Design

102 children aged 3-14 years admitted for adenotonsillectomy randomly assigned into 5 blocks in a randomized, double blind randomized clinical trial, in one of the two intravenous administration of lidocaine 2% and propofol.

Settings and conduct

In this study, children aged 3 to 14 years were candidates for adenotonsillectomy who will be referred to the Fatemiyeh Hospital of Hamedan during the study period, will be randomly assigned to randomized allocation blocks by random sampling.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Aged 3-14 years old; Candidate for elective adenotonsillectomy; Parental Satisfaction
Exclusion Criteria: Those who are reluctant to continue to participate in the study; History of Cardio-pulmonary disease; Recent infection of the upper respiratory tract and febrile illnesses; History of allergy to eggs, soy, lidocaine and propofol; difficult intubation; Corticosteroid use

Intervention groups

Intervention group 1: Children aged 3 to 14 years old are candidates for adenotonsillectomy, which will receive 2 mg / kg Lidocaine for two minutes prior to extubation.
Intervention group 2: Children aged 3 to 14 years old are candidates for adenotonsillectomy, which will receive propofol 0.5 mg / kg for two minutes prior to extubation.

Main outcome variables

Laryngospasm

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120915010841N16**

Registration date: **2019-04-24, 1398/02/04**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-24, 1398/02/04**

Update count: **0**

Registration date

2019-04-24, 1398/02/04

Registrant information

Name

Nahid Manouchehrian

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1827 7012

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-09, 1398/01/20

Expected recruitment end date

2020-04-08, 1399/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Not used
Scientific title	Assignment
The comparative Evaluation of Efficacy of intravenous lidocaine 2% and propofol in preventing laryngospasm and complications after tonsilectomy	Parallel
Public title	Other design features
Efficacy of intravenous lidocaine 2% and propofol in preventing laryngospasm	
Purpose	Secondary Ids
Treatment	empty
Inclusion/Exclusion criteria	Ethics committees
Inclusion criteria:	1
Aged 3-14 years old Candidate for elective adenotonsilectomy Parental Satisfaction	Ethics committee
Exclusion criteria:	Name of ethics committee
Those who are reluctant to continue to participate in the study History of Cardio-pulmonary disease Recent infection of the upper respiratory tract and febrile illnesses History of allergy to eggs, soy, lidocaine and propofol difficult intubation Corticosteroid use	Ethics Committee of Hamadan university of medical sciences
Age	Street address
From 3 years old to 14 years old	Mahdieh Street
Gender	City
Both	Hamadan
Phase	Province
2	Hamadan
Groups that have been masked	Postal code
• Participant • Care provider • Investigator • Data analyser	6517838678
Sample size	Approval date
Target sample size: 102	2018-12-01, 1397/09/10
Randomization (investigator's opinion)	Ethics committee reference number
Randomized	IR.UMSHA.REC.1397.628
Randomization description	
we provide ten paper sheets . We write five letters A and on five other sheets of letter B. We mix the papers together and put them in the drawer of the table. With each of the qualified patients, one of the papers is taken out randomly and, According to the text, the patient is given one of two groups: A (Propofol) and B (Lidocaine). Then, for ten subsequent patients, the paper is returned to the bag again, and this process is repeated until the end of the sample volume.	Health conditions studied
Blinding (investigator's opinion)	1
Double blinded	Description of health condition studied
Blinding description	laryngospasm and complications after tonsilectomy
In both groups A and B, medications (propofol or lidocaine) will be prescribed two minutes before the extubation of the chip. In order to prevent the medication being detectable for patients and investigators, they are prepared and injected into syringes of the same size and shape and on the adhesives A and B by the anesthetist. Since drugs are prescribed and prescribed by an anesthetist, the clinician will not be aware of the type of prescribed medication that will measure and record the outcome of the study.	ICD-10 code
Placebo	J38.5
	ICD-10 code description
	Laryngeal spasm
	Primary outcomes
	1
	Description
	laryngospasm
	Timepoint
	1, 3, 5, 10 and 15 minutes after extubation
	Method of measurement
	Observation
	Secondary outcomes
	1
	Description
	Nausea & vomiting
	Timepoint
	After surgery
	Method of measurement

Observation

2

Description

Systolic and Diastolic Blood Pressure

Timepoint

Every two minutes for 10 minutes and then every 10 minutes to 60 minute

Method of measurement

Non-invasive automatic barometric device

3

Description

Heart Rate

Timepoint

Every two minutes for 10 minutes and then every 10 minutes to 60 minute

Method of measurement

Non-invasive automatic barometric device

Intervention groups

1

Description

Intervention group: Children aged 3 to 14 years old are candidates for adenotonsillectomy, which will receive 1 mg / kg of lidocaine 2%, two minutes before extubation.

Category

Prevention

2

Description

Intervention group: Children aged 3 to 14 years old are candidates for adenotonsillectomy, which will receive 0.5 mg / kg propofol two minutes before to extubation.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Nahid Manouchehrian, Anesthesiologist, Assistant Professor of Hamadan University Of Medical Sciences

Street address

Besat Hospital in Hamadan

City

Hamadan

Province

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6517789971

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Email

hp.besat@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Nahid Manouchehrian

Position

Associate professor of Hamadan University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available