Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Inclusin Criteria: Aged 3-14 years old; Candidate for elective adenotonsilectomy; 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 Manuchehrian

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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manouchehrian@umsha.ac.ir

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

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

Public title
Efficacy of intravenous lidocaine 2% and propofol in preventing laryngospasm

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Aged 3-14 years old Candidate for elective adenotonsilectomy 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

Age
From **3 years** old to **14 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **102**

Randomization (investigator's opinion)
Randomized

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.

Blinding (investigator's opinion)
Double blinded

Blinding description
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.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hamadan university of medical sciences

Street address
Mahdieh Street

City
Hamadan

Province
Hamadan

Postal code
6517838678

Approval date
2018-12-01, 1397/09/10

Ethics committee reference number
IR.UMSHA.REC.1397.628

Health conditions studied

1

Description of health condition studied
laryngospasm and complications after tonsilectomy

ICD-10 code
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
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6517789971
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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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vc_research@umsha.ac.ir
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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Person responsible for updating data

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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