Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of three drug groups effectiveness, intravenous Lidocaine and Dexamethasone, intravenous Ketamine and Dexamethasone and Dexamethasone alone in the managment of respiratory complications after tonsillectomy.

Protocol summary

Study aim

Comparison of three drug groups effectiveness, intravenous Lidocaine and Dexamethasone, intravenous Ketamine and Dexamethasone and Dexamethasone alone in the managment of respiratory complications after tonsillectomy.

Design

Clinical trial with control group, parallel groups, double blinded, randomized on 100 patients. Random allocation law and SPSS software are used for randomization.

Settings and conduct

The study was performed on 100 tonsillectomy patients who recieved prepared drugs before extubation and respiratory complications were evaluated in recovery. The patients and the parents, the statistical researcher and the person collecting the data do not know the study group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All ASA1 patients candidates for elective tonsillectomy surgery aged 2-18 years Exclusion criteria : Active upper respiratory tract infection during the two weeks before surgery. Active lower respiratory tract infection within 5 weeks before surgery, history of asthma, history of drug allergies.

Intervention groups

Prior to extubation, each patient receives medication previously prepared in the same syringe volume of 5 cc. After obtaining the necessary conditions for extubation, they are extrubated and transferred to recovery. The first group of patients recieve Dexamethasone 0.1 mg / kg and Lidocaine 1 mg / kg, the second group recieve Ketamine 0.5 mg / kg and Dexamethasone 0.1 mg / kg, the third group recieve only Dexamethasone 0.1 mg / kg and the fourth group recieve normal saline with the same volume intravenously.

Main outcome variables

Prevention of respiratory complications after pediatric tonsillectomy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210718051928N1**
Registration date: **2021-09-06, 1400/06/15**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-06, 1400/06/15**
Update count: **0**

Registration date

2021-09-06, 1400/06/15

Registrant information

Name

Somaye Hoghughi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3240 3303

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s.hoghughi70@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-01, 1400/06/10

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of three drug groups effectiveness, intravenous Lidocaine and Dexamethasone, intravenous Ketamine and Dexamethasone and Dexamethasone alone in the managment of respiratory complications after tonsillectomy.

Public title

Comparison of three drug groups effectiveness, intravenous Lidocaine and Dexamethasone, intravenous Ketamine and Dexamethasone and Dexamethasone alone in the managment of respiratory complications after tonsillectomy.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All ASA1 patients are candidates for elective tonsillectomy Age between 2-18 years Parental consent

Exclusion criteria:

Active upper respiratory tract infection during the two weeks prior to surgery Active lower respiratory tract infection during the 5 weeks prior to surgery History of asthma History of allergy to Lidocaine , Dexamethasone and Ketamine ASA2 patients and higher

Age

From **2 years** old to **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Within the setting time we enter all patients who have the indication non-randomly. Patients are then divided into 4 groups according to the law of random allocation. The SPSS system randomly codes 100 patients, so that each patient who enters the operating room has a specific code based on how many people enter the operating room. For example, the fourth patient has code B and receives medication in this group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients in 4 groups receive the same volume of drugs and do not know the content of the drugs. The parents, the statistical researcher and the person collecting the data do not know the study group. The person preparing the medicine does not know the patients.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezarjorib Ave

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2021-08-30, 1400/06/08

Ethics committee reference number

IR.MUI.MED.REC.1400.418

Health conditions studied

1

Description of health condition studied

Respiratory complications after tonsillectomy

ICD-10 code

J04.2

ICD-10 code description

Acute laryngotracheitis

Primary outcomes

1

Description

The percentage of people whose airway irritability score is 8-10.

Timepoint

Every ten minutes after entering the recovery and the moment of leaving the recovery.

Method of measurement

Use of airway irritability questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: Dexamethasone 0.1 mg / kg and Lidocaine 1 mg / kg in a 5cc syring with the same volume witch is injected as a single dose before extubation.
Category
Prevention

2

Description
Intervention group2: Ketamine 0.5 mg / kg and Dexamethasone 0.1 mg / kg prepared in a 5cc syring witch is injected as a single dose before extubation.
Category
Prevention

3

Description
Intervention group3: Dexamethasone 0.1 mg / kg prepared in a 5cc syring with the same volume witch is injected as a single dose before extubation.
Category
Prevention

4

Description
Control group4: recieve normal saline with the same volume(5 cc) intravenous befor extubation.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan medical science educatinal Hospitals
Full name of responsible person
seyed Morteza Heidari
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan univercity of medical science
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
Esfahan University of Medical Sciences
Full name of responsible person
Somayye Hoghughi
Position
resident
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The questionnaire and statistical data will be published without individual patient data .
When the data will become available and for how long
After completing the research.
To whom data/document is available
Researchers from academic institutions will have access.
Under which criteria data/document could be used
Any kind of scientific analysis is allowed.
From where data/document is obtainable
Dr. Seyed Morteza Heidari and Somayeh Hoghughi, whose full contact information was provided in the previous sections.
What processes are involved for a request to access data/document
For a week after making the call, the information will be provided.
Comments