

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of three drug groups effectiveness, intravenous Lidocaine and Dexamethasone, intravenous Ketamine and Dexamethasone and Dexamethasone alone in the management 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 management 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 received 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 extubated and transferred to recovery. The first group of patients receive Dexamethasone 0.1 mg / kg and Lidocaine 1 mg / kg, the second group receive Ketamine 0.5 mg / kg and Dexamethasone 0.1 mg / kg, the third group receive only Dexamethasone 0.1 mg / kg and the fourth group receive 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 Haghghi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3240 3303

Email address

s.haghghi70@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 management 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 management 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

Isfahan

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 syringe with the same volume which 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 syringe which is injected as a single dose before extubation.

Category

Prevention

3

Description

Intervention group3: Dexamethasone 0.1 mg / kg prepared in a 5cc syringe with the same volume which is injected as a single dose before extubation.

Category

Prevention

4

Description

Control group4: receive normal saline with the same volume (5 cc) intravenously before extubation.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan medical science educational Hospitals

Full name of responsible person

Seyed Morteza Heidari

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Isfahan university of medical science, Hezarjarib Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Beheshte Toghyani

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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 university 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 Haghghi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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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 Haghughy, 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