

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Evaluation of the effect of intravenous lidocaine and intravenous dexamethasone on respiratory complications after adeno-tonsillectomy surgery and comparison with control group

Protocol summary

Study aim

Determining the effect of lidocaine and intravenous dexamethasone on respiratory complications after adeno-tonsillectomy surgery and comparison with control group

Design

This is a randomized double-blind clinical trial study with parallel groups, phase 3, 90 patients undergoing adeno-tonsillectomy are randomly divided into three groups.

Settings and conduct

This study is conducting from 2018 to 2021 in Isfahan educational hospitals. 90 patients who are candidates for adeno-tonsillectomy surgery enter the study according to the entry and exit criteria and are divided into three groups of lidocaine, dexamethasone and control by random allocation software. Patients and data analysts are not aware of the groups.

Participants/Inclusion and exclusion criteria

Patients are candidates for adeno-tonsillectomy, 4 to 14 years of age and ASA, anesthesia 1 or 2, no upper or lower respiratory tract infection, no history of asthma, no drug allergy, no addiction, change of anesthesia method

Intervention groups

Group 1: Lidocaine infusion 1.5 mg / kg in 15 cc Normal Saline over 10 minutes. Group 2: Dexamethasone infusion 0.2 mg / kg in 15 cc Normal Saline over 10 minutes. Group 3: control

Main outcome variables

Respiratory infections or complications such as cold, stridor, shortness of breath, decreased arterial oxygen saturation, laryngospasm and bronchospasm, intubation time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200506047322N1**

Registration date: **2020-07-31, 1399/05/10**

Registration timing: **retrospective**

Last update: **2020-07-31, 1399/05/10**

Update count: **0**

Registration date

2020-07-31, 1399/05/10

Registrant information

Name

Sara Goodarziyan

Name of organization / entity

Country

Iran (Islamic Republic of)

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sara.goodarziyan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-17, 1397/07/25

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

2018-10-19, 1397/07/27

Actual recruitment end date

2020-04-19, 1399/01/31

Trial completion date

2020-04-19, 1399/01/31

Scientific title

Evaluation of the effect of intravenous lidocaine and intravenous dexamethasone on respiratory complications

after adeno-tonsillectomy surgery and comparison with control group

Public title

Effect of intravenous lidocaine and intravenous dexamethasone on respiratory complications after adeno-tonsillectomy surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All patients are candidates for adeno-tonsillectomy surgery with an age range of 4-14 years and anesthesia ASA 1 or 2

Exclusion criteria:

Active upper respiratory tract infection within two weeks prior to surgery
Active infection of the lower respiratory tract during 5 weeks before surgery
A history of asthma
History of sensitivity to lidocaine and history of sensitivity to dexamethasone
Smoking patient

Age

From **4 years** old to **14 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants in the present study were coded. Codes enter Random Allocation Software and divide by randomly blocking method into 2 groups of intervention and the control group with senary blocks and a ratio of 1:1 . In order to conceal the allocation; The groups were placed in similar envelopes in a matte package numbered consecutively. Blocking and preparation of envelopes was performed by a person who is not involved in sampling and data analysis.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients have no information about the medication they receive. The information enters the software with the code and the analyst is unaware of the allocation of groups. After finishing and analyzing the data, the codes are opened

Placebo

Not 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

Hezar Jarib street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-04-29, 1399/02/10

Ethics committee reference number

IR.MUI.MED.REC.1399.088

Health conditions studied

1

Description of health condition studied

adeno-tonsillectomy

ICD-10 code

J35

ICD-10 code description

Chronic diseases of tonsils and adenoids

Primary outcomes

1

Description

Respiratory complications

Timepoint

Up to 15 minutes per minute after injection of the drug and then every 15 minutes until discharge from recovery

Method of measurement

Airway Irritability Rating Score

Secondary outcomes

1

Description

Hemodynamic disorders

Timepoint

Up to 15 minutes per minute after injection of the drug and then every 15 minutes until discharge from recovery.

Method of measurement

pulse oximeter

2

Description

Recovery time

Timepoint

From the beginning of the drug injection to the end of recovery

Method of measurement

Measuring time (minutes)

Intervention groups**1****Description**

Intervention group 1: Lidocaine intravenous infusion of 1.5 mg / kg in 15 cc normal saline within 10 minutes

Category

Prevention

2**Description**

Intervention group 2: Dexamethasone intravenous infusion 0.2 mg / kg in 15 cc normal saline within 10 min

Category

Prevention

3**Description**

Control group: without any drug

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kashani Hospital

Full name of responsible person

Kamran Montazeri

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2**Recruitment center****Name of recruitment center**

Alzahra Hospital

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3**Recruitment center****Name of recruitment center**

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

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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

Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Kamran Montazeri
Position
Professor
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The information belongs to the government agency.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Because the information belongs to the government agency, it is not possible to share it.

When the data will become available and for how long

no time

To whom data/document is available

nobody

Under which criteria data/document could be used

Under no circumstances

From where data/document is obtainable

No one, nowhere

What processes are involved for a request to access data/document

No process

Comments