Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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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+98 31 3668 0048

Email address
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
Isfehan
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
Street address
Kashani Street
City
Isfahan
Province
Isfehan
Postal code
8183983434
Phone
+98 31 3233 0091
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montazeri@med.mui.ac.ir

2

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Kamran Montazeri
Street address
Shohadaye sofe Boulevard
City
Isfahan
Province
Isfehan
Postal code
8174675731
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+98 31 3668 5555
Email
montazeri@med.mui.ac.ir

3

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Kamran Montazeri
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8195163381
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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haghjoo@med.mui.ac.ir
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

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

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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