Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study on the efficacy of intravenous dexamethasone and lidocaine in reducing respiratory complications after general anesthesia in children with a history of reactive airways

Protocol summary

Study aim

Since no previous studies have compared the efficacy of dexamethasone and lidocaine in preventing the incidence of respiratory complications after extubation in children with a history of reactive airways, this study sought to compare the effects of these two drugs in decreasing the mentioned complications in children with reactive airways.

Design

This randomized double-blind clinical trial will conduct at Imam Hossein Pediatric Hospital

Settings and conduct

The double-blind design will ensure by keeping the patient, the person who injected the medicines, and the data collector unaware of the group allocations.

Participants/Inclusion and exclusion criteria

healthy one-six-year-old ASA I/ASA II candidates of inguinal hernia repair who had a history of reactive airways or cold symptoms in the past six weeks were included. The exclusion criteria were fever, productive cough, rhonchi in lung auscultation, prolonged surgery (longer than one hour), bleeding, and any complications of the surgery.

Intervention groups

An anesthesiologist prepar equal volumes of medications in similar syringes. Before the induction of anesthesia by the nurse, the first, second, and third groups receive intravenous dexamethasone (0.2 mg/kg), intravenous lidocaine (1 mg/kg), and placebo (normal saline with similar volume),

Main outcome variables

After patient transfer to the post-anesthesia care unit (PACU), the researcher record SPO2, MAP, heart rate, and respiratory complications (cough, laryngospasm, bronchospasm, every 15 minutes. Moreover, the same parameters will evaluate every two hours during the first six hours of the patient’s stay in the ward.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160301026866N5**
Registration date: **2018-06-20, 1397/03/30**
Registration timing: **prospective**

Last update: **2018-06-20, 1397/03/30**
Update count: **0**

Registration date

2018-06-20, 1397/03/30

Registrant information

Name

Amir Shafa

Name of organization / entity

Isfahan University of Medical Sciences, Imam hossein Hospital

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
A comparative study on the efficacy of intravenous dexamethasone and lidocaine in reducing respiratory complications after general anesthesia in children with a history of reactive airways

Public title
A comparative study on the efficacy of intravenous dexamethasone and lidocaine in reducing respiratory complications after general anesthesia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
healthy one-six-year-old ASA I/ASA II candidates of inguinal hernia repair who had a history of reactive airways or cold symptoms in the past six weeks were included.
Exclusion criteria:
fever, productive cough, rhonchi in lung auscultation

Age
From **1 year** old to **6 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple Random Allocation

Blinding (investigator's opinion)
Double blinded

Blinding description
The double-blind design was ensured by keeping the patient, the person who injected the medicines, and the data collector unaware of the group allocations

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics commottee of Isfahan University Of Medical Sciences
Street address
Hezarjerib Ave.
City
Isfahan
Province
Isfehan
Postal code
8185665843

Approval date
2016-06-25, 1395/04/05

Ethics committee reference number
ir.mui.rec.1395.3.94975

Health conditions studied

1

Description of health condition studied
respiratory complications after general anesthesia

ICD-10 code
J40

ICD-10 code description
J20

Primary outcomes

1

Description
SPO2, respiratory complications (cough, laryngospasm, bronchospasm)

Timepoint
every 15 minutes in the ricovery room and every two hours during the first six hours of the patient’s stay in the ward

Method of measurement
Pulse Oximeter

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Before the induction of anesthesia by the nurse, the first, second, and third groups received intravenous dexamethasone (0.2 mg/kg), intravenous lidocaine (1 mg/kg), and placebo (normal saline with similar volume), respectively.

Category
Treatment - Drugs

2

Description
Control group:placebo(normal saline)with similar volume
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Hossein Hospital
Full name of responsible person
Amir Shafa
Street address
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Sponsors / Funding sources

1

Sponsor
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Shaghayegh Haghjoo
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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
Amir Shafa
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All files

When the data will become available and for how long
6 Month after print results

To whom data/document is available
All peoples

Under which criteria data/document could be used
There are no special conditions

From where data/document is obtainable
Amir Shafa Email: amir_shafa@med.mui.ac.ir

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

Comments