

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 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)

Phone

+98 31 3627 2655

Email address

amir_shafa@med.mui.ac.ir

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 committee of Isfahan University Of Medical Sciences

Street address

Hezarjerib Ave.

City

Isfahan

Province

Isfahan

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 recovery 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

Emam Hossein Hospital,Emam Khomeini Ave.

City

Isfahan

Province

Isfahan

Postal code

8185665843

Phone

+98 31 3386 9141

Email

amir_shafa@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Hezarjerib Ave.

City

Isfahan

Province

Isfahan

Postal code

8185665843

Phone

+98 31 3668 8138

Email

sh_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

Amir Shafa

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Emam Hossein Hospital, Emam Khomeini Ave

City

Isfahan

Province

Isfahan

Postal code

8185665843

Phone

+98 31 3773 5509

Email

amir_shafa@med.mui.ac.ir

Person responsible for scientific 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

Anesthesiology

Street address

Emam Hossein Hospital, Emam khomeini Ave

City

Isfahan

Province

Isfahan

Postal code

8185665843

Phone

+98 31 3773 5509

Email

amir_shafa@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

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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