

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

A comparative study on the effect of intravenous dexamethasone and intravenous lidocaine on reduction of hemodynamic and respiratory complications in children undergoing cleft palate surgery

Protocol summary

Study aim

The effect of intravenous dexamethasone and lidocaine on reduction of respiratory and hemodynamics complications after general anesthesia in children undergoing cleft palate surgery.

Design

This study is a randomized double-blind, clinical trial with parallel groups.

Settings and conduct

This study will be carried out among patients undergoing cleft palate surgery at Imam Hossein Hospital in Isfahan, Iran, in 2018. The drugs are in equal volumes and are encrypted in the same syringes. In addition the syringes will be coded. These jobs will be done to keep blinding. Patients, researcher and nurse-recorder do not know which group the patients are allocated to.

Participants/Inclusion and exclusion criteria

Inclusion criteria : candidates of cleft palate repair surgery with age range of 6 months old to 2 years old and patients with class I and II in American society of anesthesiologists (ASA) classification. Exclusion criteria: prolonged surgical time more than 3 hours, post-operative bleeding and post-surgical complication

Intervention groups

The first group received intravenous dexamethasone (0.2 mg / kg), the second group received intravenous lidocaine (1 mg / kg) and the third group received placebo. The drugs were in equal volumes and they were prescribed before induction of anesthesia.

Main outcome variables

Mean arterial blood pressure; Heart rate; Severity of pain; Laryngospasm; Bronchospasm; Cough; Vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160301026866N8**

Registration date: **2018-09-17, 1397/06/26**

Registration timing: **prospective**

Last update: **2019-01-07, 1397/10/17**

Update count: **1**

Registration date

2018-09-17, 1397/06/26

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

2018-09-20, 1397/06/29

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the effect of intravenous dexamethasone and intravenous lidocaine on reduction of hemodynamic and respiratory complications in children undergoing cleft palate surgery

Public title

Intravenous Dexamethasone and intravenous lidocaine in children undergoing cleft palate surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Six months to two years children with ASA class I and II without underlying illness candidate for Cleft palate surgery

Exclusion criteria:

The presence of symptoms of upper respiratory tract infection Coagulation disorder Systemic diseases other hereditary abnormalities

Age

From **6 months** old to **2 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **115**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization with using Permuted block randomization, For this purpose, use 6-unit blocks. We start randomly from the number 4480 in the random number table And up to 7045, we will code a total of 18 blocks of 6 by the table.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients, researcher and nurse-recorder do not know which group the patients are allocated to. Medications are prepared in similar syringes and in equal volumes.

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

Emamhossein Hospital, Emam Khomeini Ave.

City

Isfahan

Province

Isfahan

Postal code

8185665843

Approval date

2015-08-11, 1394/05/20

Ethics committee reference number

Ir.Mui.Rec.1394.3.873

Health conditions studied

1

Description of health condition studied

Respiratory and hemodynamic complications in the cleft palate

ICD-10 code

Q35; Q36;

ICD-10 code description

Cleft palate; Cleft lip; Cleft palate with cleft lip

Primary outcomes

1

Description

Mean arterial blood pressure

Timepoint

Every 15 minutes during surgery and every 15 minutes in recovery room

Method of measurement

Anesthetic monitoring device

2

Description

Heart rate

Timepoint

Every 15 minutes during surgery and every 15 minutes in recovery room

Method of measurement

Anesthetic monitoring device

3

Description

Respiratory complications(Larangospasm, bronchospasm, coughing)

Timepoint

in the recovery room

Method of measurement

Recording the complications

4

Description

Intensity of pain

Timepoint

Every 15 minutes in recovery room

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Before induction of anesthesia, a recovery nurse will be administered to the first group of intravenous dexamethasone (0.2 mg / kg).

Category

Treatment - Drugs

2

Description

Intervention group 2: Before induction of anesthesia, a recovery nurse will be administered to the second group of intravenous lidocaine (1mg / kg).

Category

Treatment - Drugs

3

Description

Control group: Placebo is given in equal volume.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein hospital

Full name of responsible person

Amir Shafa

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Imam Hossein hospital, Imam Khomeini Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Isfahan University of Medical Sciences, Hezarjrib street

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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

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
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Position
Assistant professor
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Other areas of specialty/work
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Person responsible for updating data

Contact

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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 data is shared

When the data will become available and for how long

6 months after printing results

To whom data/document is available

All researchers

Under which criteria data/document could be used

For scientific research

From where data/document is obtainable

Amir Shafa

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

Requested by email

Comments