

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

A comparative study on the effect of intravenous administration of Lidocaine and Dexamethasone on the prevention of Fentanyl induced cough in the induction of anesthesia in children under general anesthesia

Protocol summary

Study aim

Comparison of Dexamethasone and Lidocaine Effects on Coughing Reduction after Fentanyl Injection In General Anesthesia

Design

The present study is a double-blind randomized clinical trial with parallel control group. The first group will receive 1 mg / kg of intravenous lidocaine five minutes before administration of fentanyl. The second group will receive 0.2 mg / kg of dexamethasone five minutes before administration of fentanyl. The control group will receive the same volume of normal saline 0.9% five minutes prior to the administration of fentanyl.

Settings and conduct

This study is carried out in Isfahan Imam Hossein Children's Hospital. All patients received intravenous midazolam 0.1 mg / kg and will be taken in the operating room. Five minutes before receiving anesthesia, they receive the drug (lidocaine / dexamethasone / normal saline). Medications are delivered by the researcher in equal volumes and anesthetist who inject drugs and patients are blinded from groups .

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children from six months to two years, ASA I ,ASA II, Surgical candidate under general anesthesia. Exclusion criteria: Symptoms of colds in the last two week, History of reactive airway disease, The probability of difficult intubation

Intervention groups

The first group will receive 1 mg / kg of intravenous lidocaine five minutes before administration of fentanyl. The second group will receive 0.2 mg / kg of dexamethasone five minutes before administration of fentanyl. The third group will receive the same volume of normal saline 0.9% five minutes prior to the administration of fentanyl.

Main outcome variables

Incidence and severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160301026866N10**

Registration date: **2018-12-02, 1397/09/11**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-02, 1397/09/11**

Update count: **0**

Registration date

2018-12-02, 1397/09/11

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

2018-10-02, 1397/07/10

Expected recruitment end date

2019-01-30, 1397/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the effect of intravenous administration of Lidocaine and Dexamethasone on the prevention of Fentanyl induced cough in the induction of anesthesia in children under general anesthesia

Public title

A comparative study on the effect of intravenous administration of Lidocaine and Dexamethasone on the prevention of Fentanyl induced cough in the induction of anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children from six months to two years, ASA I ,ASA II, Surgical candidate under general anesthesia

Exclusion criteria:

Symptoms of colds in the last two week, History of reactive airway disease, The probability of difficult intubation

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **121**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method Using the random number table

Blinding (investigator's opinion)

Double blinded

Blinding description

Medications are delivered by the researcher in equal volume, Encoded, Anesthesiologist who inject drugs and patients from groups is not known

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

Hezarjrib Ave, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

8185665843

Approval date

1997-09-01, 1376/06/10

Ethics committee reference number

ir.mui.rec.1396.3.371

Health conditions studied**1****Description of health condition studied**

Fentanyl-induced coughing

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

incidence and Severity of coughing

Timepoint

One minute after prescribing the drug, One minute after the administration of fentanyl

Method of measurement

Standard questionnaire

Secondary outcomes

empty

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

Control group: Five minutes before prescribing fentanyl, 1 cc normal saline will receive .

Category

Treatment - Drugs

2**Description**

Intervention group1: 5 minutes before administration of fentanyl, 1 mg / kg intravenous lidocaine will receive .

Category

Treatment - Drugs

3

Description

Intervention group2: 5 minutes before administration of fentanyl, 0.2 mg / kg intravenous Dexamethasone will receive .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam hossein Children Hospital

Full name of responsible person

Amir shafa

Street address

Emam Khomeini Ave, Emam Hossein Hospital

City

Isfahan

Province

Isfahan

Postal code

8185665843

Phone

+98 31 3773 5509

Email

shafa_amir@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shghayegh haghjoo

Street address

Hezarjrib Ave, Isfahan University of Medical Sciences

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 khomeini Ave, Emamhossein Hospital

City

Isfahan

Province

Isfahan

Postal code

81856665843

Phone

+98 31 3773 5509

Email

shafa_amir@yahoo.com

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 khomeini Ave, Emamhossein Hospital

City

Isfahan

Province

Isfahan

Postal code

8185665843

Phone

+98 31 3773 5509

Email

Person responsible for updating data

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

Emamkhomeini Ave, Emamhossein Hospital

City

Isfahan

Province

Isfahan

Postal code

8185665843

Phone

+98 31 3773 5509

Email

shafa_amir@yahoo.com

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

The total potential data can be shared after unidentifiable people

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Access for everyone is free

Under which criteria data/document could be used

There are no special conditions.

From where data/document is obtainable

Amir Shafa: shafa_amir@yahoo.com

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

Request via email

Comments