

# 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 weeks, 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

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**Province**

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**Postal code**

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**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

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Hezarjrib Ave, Isfahan University of Medical Sciences

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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**

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## 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**

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**