

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Comparison of the effect of pretreatment Intravenous lidocaine with fentanyl for suppression of fentanyl induced cough in children

#### Protocol summary

##### Summary

Fentanyl is commonly used as a pre-induction adjunct and can cause fentanyl induced cough. In this study we want to compare the effect of pretreatment lidocaine with fentanyl for suppression of fentanyl induced cough in pediatric patients. This study will perform on 99 Patients of either gender. Inclusion criteria will be ASA I ,II, aged 2 to 10 years old who are scheduled for elective hernioraphy under general anesthesia in Urmia Motahari Hospital, are enrolled in the study. Exclusion criteria include patients with body weight more than 20% of the ideal body weight, emergency hernioraphy, a history of asthma, chronic obstructive lung diseases, chronic cough, upper respiratory tract infection within 4 weeks of Surgery, children with malformation of the tongue and oropharynx, and allergy to the study drugs. All patients will receiving an oral administration of 0.3 mg/kg of midazolam 30 minutes before separation from parents or IV (0.5 mg) and atropine (0.02 mg/kg) when IV access are established before the induction of anesthesia. Patients will randomly allocated using the sealed envelope technique in three groups of 33 each to receive: 1.0 mg/kg lidocaine (I), 0.5 µg/kg fentanyl (II) or placebo equal volume of 0.9% saline (III), 1 min before the IV administration of 2 µg/kg fentanyl over 2second during induction of general anesthesia. A blinded observer, who is not aware of the type of medication given to the patients, will recorded the number of coughing episodes until to 2 minute.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016112027677N5**

Registration date: **2017-01-02, 1395/10/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-01-02, 1395/10/13

##### Registrant information

###### Name

Shahryar Sane

###### Name of organization / entity

Urmia University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 44 3223 4897

###### Email address

sane.sh@umsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

investigator

##### Expected recruitment start date

2015-12-22, 1394/10/01

##### Expected recruitment end date

2016-05-21, 1395/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of pretreatment Intravenous lidocaine with fentanyl for suppression of fentanyl induced cough in children

##### Public title

Clinical trial effect of Intravenous lidocaine with fentanyl for suppression of fentanyl induced cough in children

##### Purpose

Prevention

### **Inclusion/Exclusion criteria**

Inclusion criteria: Anesthesiologists physical status I, II; aged 2 to 10 years old; elective hernioraphy; general anesthesia  
Exclusion criteria: patients with body weight less than 20% of the ideal body weight; emergency hernioraphy; a history of asthma; chronic obstructive lung diseases; chronic cough; upper respiratory tract infection within 4 weeks of Surgery; children with malformation of the tongue and oropharynx; allergy to the study drugs

### **Age**

From **2 years** old to **10 years** old

### **Gender**

Both

### **Phase**

2-3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **99**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

The intervening person will inject the drugs to the patient based on the random numbers table.

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Urmia University of Medical Sciences

##### **Street address**

Emergent Street, Resalat avenue, Urmia

##### **City**

Urmia

##### **Postal code**

5714783734

#### **Approval date**

2010-09-23, 1389/07/01

#### **Ethics committee reference number**

ir.umsu.rec.1394.386

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Opioid induced cough

#### **ICD-10 code**

A37.9

#### **ICD-10 code description**

Whooping cough, unspecified

## **Primary outcomes**

### 1

#### **Description**

cough

#### **Timepoint**

Within 2 minutes after fentanyl injection

#### **Method of measurement**

patient observation

## **Secondary outcomes**

### 1

#### **Description**

Mean Arterial Blood Pressure

#### **Timepoint**

Within 2 minutes after fentanyl injection

#### **Method of measurement**

None Invasive Blood Pressure

### 2

#### **Description**

Pulse rate

#### **Timepoint**

Within 2 minutes after fentanyl injection

#### **Method of measurement**

Electrocardiogram

### 3

#### **Description**

The percentage of arterial oxygen

#### **Timepoint**

Within 2 minutes after fentanyl injection

#### **Method of measurement**

Pulse Oximetry

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: Fentanyl will be prepared in 5 cc syringes randomly injected.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group 2: lidocaine will be prepared in 5 cc syringes and after closing cord randomly injected.

**Category**

Treatment - Drugs

**3**

**Description**

Control group: Normal Saline will be prepared in 5 cc syringes randomly injected.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Motahhari Hospital

**Full name of responsible person**

Shahryar Sane

**Street address**

Kashani Avenue

**City**

Urmia

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Urmia University of Medical Sciences

**Full name of responsible person**

Shahryar Sane

**Street address**

Emergent Street, Resalat avenue, Urmia

**City**

Urmia

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Urmia University of Medical Sciences

**Proportion provided by this source**

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**2**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for research of Urmia University of Medical Sciences

**Full name of responsible person**

Shahryar Sane

**Street address**

Emergent Street, Resalat avenue, Urmia

**City**

Urmia

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for research of Urmia University of Medical Sciences

**Proportion provided by this source**

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Vice chancellor for research, Urmia University of Medical Sciences

**Full name of responsible person**

Shahryar Sane

**Position**

Assistant Professor

**Other areas of specialty/work**

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Motahhari Hospital, Department of Anesthesiology

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**Other areas of specialty/work**

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dr.sh.sane@gmail.com

**Web page address**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*