

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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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Person responsible for scientific inquiries

Contact

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Shahryar Sane

Position

Assistant Professor

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