Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 to10 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 commitee 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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Contact

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Person responsible for updating data

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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