Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of low dose Propofol on fentanyl-induced cough during induction of anesthesia.

Protocol summary

Summary

The aim of this randomized double-blind clinical trial is to evaluate effect of low dose Propofol on fentanyl-induced cough during induction of anesthesia. A total of 240 patients, meeting eligibility criteria, will be randomly allocated into two equal groups. After establishing routine monitors, vital sign profiles (blood pressure, heart rate and Spo2) are measured and serve as baseline values. Patients in group A received Propofol (10mg) and patients in group B received the same volume of normal saline (control group). All syringes containing Propofol or placebo were covered with masking tape to conceal any details of product or volume. Two minutes later, all patients were given fentanyl (2µg/kg) over 2 seconds via the peripheral IV line in the forearm. The vital sign profiles and frequency and intensity of cough will be recorded within two minutes after fentanyl bolus by a nurses blinded to study design. The intensity of cough was arbitrarily graded as the following: no cough (None), 1-2 cough (Mild), 3-4 cough (Moderate) and 5 cough or more (Severe).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305216803N4**
Registration date: **2013-08-04, 1392/05/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-08-04, 1392/05/13

Registrant information

Name

Abolfazl Firouzian

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-07-23, 1392/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of low dose Propofol on fentanyl-induced cough during induction of anesthesia.

Public title

Effect of Propofol on fentanyl-induced cough

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Informed written consent; ASA class I-II; Age between 18 - 50 years; Various elective surgical procedures under general anesthesia. Exclusion criteria: History of asthma, chronic cough, lung disease; Smoking or substance abuse; Cardiac disease; Any disease or surgery of trachea or larynx; Upper respiratory tract infection in the previous four weeks; Impaired kidney or liver functions; Pregnancy and lactation; Medication with

angiotensin-converting enzyme inhibitors (ACE), steroids, bronchodilators, antihistamine or antitussive drugs in the previous four weeks.

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **240**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences

Street address
Mazandaran University of Medical Sciences, Moallem Square.

City
Sari

Postal code
4817844718

Approval date
2012-10-17, 1391/07/26

Ethics committee reference number
91-135

Health conditions studied

1

Description of health condition studied
fentanyl-induced cough

ICD-10 code
Y45.0

ICD-10 code description
Complications of medical and surgical care,Opioids and related analgesics

Primary outcomes

1

Description
Cough

Timepoint
Within two minutes after fentanyl injection

Method of measurement
Record in Questionnaire

Secondary outcomes

1

Description
Systolic blood pressure

Timepoint
First and two minutes after fentanyl injection

Method of measurement
Noninvasive arterial blood pressure

2

Description
Diastolic blood pressure

Timepoint
First and two minutes after fentanyl injection

Method of measurement
Noninvasive arterial blood pressure

3

Description
Mean arterial blood pressure

Timepoint
First and two minutes after fentanyl injection

Method of measurement
Noninvasive arterial blood pressure

4

Description
Heart rate

Timepoint
First and two minutes after fentanyl injection

Method of measurement
electrocardiogram

5

Description
Oxygen saturation

Timepoint
First and two minutes after fentanyl injection

Method of measurement
Pulse oxymeter

Intervention groups

1

Description
10 mg Propofol and two minutes later, 2µg/kg fentanyl
Category
Treatment - Drugs

2

Description
1 ml normal saline and two minutes later, 2µg/kg fentanyl
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Khomeini Hospital
Full name of responsible person
Abolfazl Firouzian MD, Assistant Professor
Street address
Emam Khomeini Hospital, Amir mazandarani Ave.
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mazandaran University of Medical Sciences
Full name of responsible person
Ahmad Ali Enayati MD
Street address
Mazandaran University of Medical Sciences, Moallem Square.
City
Sari
Grant name
10506
Grant code / Reference number
91-135
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Mazandaran University of Medical Sciences
Proportion provided by this source
100
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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Abolfazl Firouzian MD
Position
Anesthesiologist, Assistant Professor
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
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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