

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

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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

Street address

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Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Abolfazl Firouzian MD

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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