

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Effect of Propofol, Ketamin and combination of Propofol and Ketamine in prevention of coughing and laryngospasm in patients awakening from general anesthesia

Protocol summary

Summary

The aim of present study was to compared the effect of small doses of propofol, ketamine and their combination on presence and severity of coughing and laryngospasm. It is a double blinded clinical trial. Inclusion criteria: ASA class I or II, aged between 7 to 75 years old. Exclusion: bronchial asthma, allergic disorders, upper respiratory infection symptom during the surgery, smoking, medication with ACE inhibitors ,allergic reaction to administered drugs and changing the anesthesia technique. Study population: patients who were scheduled to undergo operations under general anesthesia . Sample size:160 patients. Routine anesthesia was performed. Patient was set at one of the following groups randomly: propofol group (received propofol 0.25 mg/kg), Ketamine (received ketamine 0.25 mg/kg), combination (with the same doses) and control group (received saline 0.1 ml/kg). . when the patient's breathing returned to regular spontaneous pattern, or when the patient opened his eyes or made purposeful movements drugs were injwcted.Occurrence and severity of laryngospasm and coughing within 2 minutes after extubation were recorded.then presence and severity of coughing and laryngospasm were recordr in 2 min after extubation. Grading of laryngospasm 0: no symptoms; 1: stridor; 2: total occlusion of the cords (respiratory efforts with no air movement); 3: cyanosis with evidence for airway obstruction at the level of vocal cords. Grading of coughing : 0: no incidence of coughing 1: only one cough 2: two coughs to slight coughing 3: severe or repetitive coughing was Frequency and severity of coughing and laryngospasm was compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403255362N18**

Registration date: **2014-05-31, 1393/03/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-31, 1393/03/10

Registrant information

Name

Mohammadreza Safavi

Name of organization / entity

Anesthesiology and Critical Care Research Center,
Isfahan University of Medical Sciences, Isfahan

Country

Iran (Islamic Republic of)

Phone

+98 31 1273 2659

Email address

safavi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2011-03-20, 1389/12/29

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Propofol, Ketamin and combination of Propofol and Ketamine in prevention of coughing and laryngospasm in patients awakening from general anesthesia

Public title

Effect of Propofol, Ketamin and their combination on post operative coughing

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: American Society of Anesthesiologists (ASA) class I or II; age between 7 to 75 years old; either sex
exclusion criteria: history of sleep apnea syndrome; developmental disorders, airway or facial abnormalities; bronchial asthma; allergic disorders; upper respiratory infection symptom during the surgery; smoking; medication with ACE inhibitors or ; occurrence of allergic reaction ; need to change the anesthesia technique.

Age

From **17 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **160**

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**

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezarjarib St, Isfahan, Iran

City

Isfahan

Postal code**Approval date**

2010-09-23, 1389/07/01

Ethics committee reference number

390523

Health conditions studied**1****Description of health condition studied**

post extubation coughing and laryngospasm

ICD-10 code

J95.8

ICD-10 code description

Other postprocedural respiratory disorders

Primary outcomes**1****Description**

coughing

Timepoint

between 1 and 3min after intervention

Method of measurement

observation

2**Description**

Laryngospasm

Timepoint

between 1 and 3min after intervention

Method of measurement

observation

Secondary outcomes

empty

Intervention groups**1****Description**

control group: received propofol 0.1 ml/kg normal saline, intravenously, when the patient's breathing returned to regular spontaneous pattern, or when the patient opened his eyes or made purposeful movements

Category

Treatment - Drugs

2**Description**

propofol group: received propofol 0.25 mg/kg, intravenously, when the patient's breathing returned to regular spontaneous pattern, or when the patient opened his eyes or made purposeful movements

Category

Treatment - Drugs

3**Description**

Ketamine group: received ketamine 0.25 mg/kg, Intravenously, when the patient's breathing returned to regular spontaneous pattern, or when the patient opened his eyes or made purposeful movements

Category

Treatment - Drugs

4**Description**

combination group:propofol group:received propofol and ketamine each one, 0.25 mg/kg, Intravenously, when the patient's breathing returned to regular spontaneous pattern, or when the patient opened his eyes or made purposeful movements

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ayatollah Kashani Hospital

Full name of responsible person

Mohammadreza Safavi Homami

Street address

Department of Anesthesiology, Al zahra Hospital, Sofe Blv, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Mansoor Siavash

Street address

Isfahan University of Medical Science,Hezarjarib st,Isfahan,Iran

City

Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Isfahan 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****Name of organization / entity**

Isfahan University of Medical sciences

Full name of responsible person

Seyyed Mohammad Reza Safavi Homami

Position

Associsted Professor, Department of Anesthesiology

Other areas of specialty/work**Street address**

Department of Anesthesiology Al-Zahra Hospital, Sofe Blv Isfahan

City

Isfahan

Postal code

8174675731

Phone

+98 31 1624 9031

Fax**Email**

safavi@med.mui.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Isfahan University of Medical sciences

Full name of responsible person

Seyyed Mohammad Reza Safavi Homami

Position

Associsted Professor, Department of Anesthesiology

Other areas of specialty/work**Street address**

Department of Anesthesiology Al-Zahra Hospital, Sofe Blv Isfahan

City

Isfahan

Postal code**Phone**

+98 31 1624 9031

Fax**Email**

safavi@med.mui.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Isfahan University of Medical sciences

Full name of responsible person

Seyyed Mohammad Reza Safavi Homami

Position

Associsted Professor, Department of Anesthesiology

Other areas of specialty/work

Street address

Department of Anesthesiology Al-Zahra Hospital, Sofe
Blv, Isfahan

City

Isfahan

Postal code**Phone**

+98 31 1624 9031

Fax**Email**

safavi@med.mui.ac.ir

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