

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

A comparison of effect of pretreatment with intravenous dexamethasone, intravenous ketamine and their combination for suppression of remifentanyl induced cough: a randomized, double-blind, placebo controlled clinical trial

Protocol summary

Summary

The injection of remifentanyl can cause cough during induction of anesthesia. This study was designed to examine the efficacy of ketamine, dexamethasone and their combination on remifentanyl-induced cough (RIC). One hundred twenty patients scheduled for elective surgery were randomly assigned into four groups: Group K received 10 mg ketamine; Group D received 10 mg dexamethasone; Group KD received 10 mg ketamine in combination with dexamethasone; Group S received saline in similar volume five minutes prior to the injection of remifentanyl. The incidence and severity of coughs were recorded in each person.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210255362N4**

Registration date: **2012-11-11, 1391/08/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-11-11, 1391/08/21

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

2011-11-22, 1390/09/01

Expected recruitment end date

2012-04-20, 1391/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of effect of pretreatment with intravenous dexamethasone, intravenous ketamine and their combination for suppression of remifentanyl induced cough: a randomized, double-blind, placebo controlled clinical trial

Public title

A comparison of effect of pretreatment with intravenous dexamethasone, intravenous ketamine and their combination for suppression of remifentanyl induced cough

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: patient satisfaction to enter study;
body weight less than 20% of ideal body weight; no
history of smoking, chronic obstructive lung diseases,

bronchial asthma, respiratory tract infection or allergy to the study drugs; treated with angiotensin converting enzyme inhibitor, bronchodilators or steroid Exclusion criteria: any changes in anesthesia technique

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

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, Isfahan, Iran

Street address

Isfahan University of Medical Sciences, Isfahan, Iran

City

Isfahan

Postal code

8174675731

Approval date

2011-11-05, 1390/08/14

Ethics committee reference number

391239

Health conditions studied

1

Description of health condition studied

cough

ICD-10 code

R05

ICD-10 code description

cough

Primary outcomes

1

Description

Severity of cough

Timepoint

5 minute After injection of remifentanyl

Method of measurement

counting

2

Description

Incidence of cough

Timepoint

5 minute After injection of remifentanyl

Method of measurement

watch

3

Description

onset time of cough

Timepoint

5 minute After injection of remifentanyl

Method of measurement

watch

Secondary outcomes

1

Description

Haemodynamic

Timepoint

immediately after arriving at operation room, immediately after injection of remifentanyl, immediately after injection of tiopental

Method of measurement

watch

2

Description

side effect

Timepoint

every hour

Method of measurement

watch

Intervention groups

1

Description

Group ketamine: 10 mg of ketamine in 3ml volume+3 ml saline was injected.

Category

Prevention

2

Description

Group saline: the same volume of saline was injected .

Category

Prevention

3

Description

Group combination of ketamine and dexamethasone: 10 mg of combination of ketamine and dexamethasone in 3ml volume+3 ml saline was injected.

Category

Prevention

4

Description

Group dexamethasone:10 mg of dexamethasone in 3ml volume+3 ml saline was injected .

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

Dr. Mohammadreza Safavi

Street address

Kashani street, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Azim Honarmand

Street address

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

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

Full name of responsible person

Dr. Mohammadreza Safavi

Position

Associate Professor of Anesthesia

Other areas of specialty/work

Street address

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

City

Isfahan

Postal code

8174675731

Phone

+98 31 1625 5555

Fax

+98 31 1273 2659

Email

safavi@med.mui.ac.ir

Web page address

www.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

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

Full name of responsible person

Dr. Azim Honarmand

Position

Associate Professor of Anesthesia

Other areas of specialty/work

Street address

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

City

Isfahan

Postal code

8174675731

Phone

+98 31 1273 2659

Fax

+98 31 1236 1594

Email

honarmand@med.mui.ac.ir

Web page address

www.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

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

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Mohammadreza Safavi

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Fax

+98 31 1273 2659

Email

safavi@med.mui.ac.ir

Web page address

www.mui.ac.ir

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