Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Nov 2026

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

Protocol summary

Summary
The injection of remifentanil can cause cough during induction of anesthesia. This study was designed to examine the efficacy of ketamine, dexamethasone and their combination on remifentanil-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 remifentanil .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
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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 remifentanil 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 remifentanil 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 remifentanil

Method of measurement
counting

2

Description
Incidence of cough

Timepoint
5 minute After injection of remifentanil

Method of measurement
watch

3

Description
onset time of cough

Timepoint
5 minute After injection of remifentanil

Method of measurement
watch

Secondary outcomes

1

Description
Haemodynamic

Timepoint
immediately after arriving at operation room,immediately after injection of remifentanil,immediately after injection of tiopantal

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
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Anesthesiology and Critical Care Research Center, Isfahan University of Medical Sciences, Isfahan, Iran
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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
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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