Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of hemodynamic changes of propofol -ketamine with propofol-fentanyl in induction of anesthesia in smokers

Protocol summary

Summary

Purpose: The aim of this study was the evaluation of hemodynamic effects of the drugs that are commonly used in anesthesia to evaluate which anesthetic causes fewer changes in smokers. Design and criteria: 64 smokers patients, with ASA I-II and 18-60 years of age who are undergoing general anesthesia were enrolled. Patients with a history of hypertension, coronary artery disease, seizure, psychiatric disease, liver or kidney disease, drug abuse, hypersensitivity to fentanyl, ketamine, propofol and atracurium are excluded. Methods: Before induction, all patients receive ringer 5 cc/kg. The monitoring of ECG, heart rate, pulse oximetry and noninvasive blood pressure measurement is performed. In first group we inject 1 mg midazolam, 0.5 mg/kg ketamine and 2 mg/kg propofol with rate of 80 mg/kg/h. In second group we administrate 2 microgr/kg fentanyl instead ketamine. After eye reflex loss, atracurium 0.5 mg / kg is injected. After 2-3 min the patients are intubated with endotracheal tube. Anesthesia is maintained with propofol 100 microgr/kg and O2-N2O 50%. Primary outcomes: Vital signs, including systolic blood pressure, diastolic blood pressure and heart rate before induction, before and after intubation and then every 5 minutes until half-an-hour are measured and recorded. Also laryngospasm and bronchospasm are evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305099229N2**
Registration date: **2013-05-25, 1392/03/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-05-25, 1392/03/04

Registrant information

Name
Mehryar Taghavi Gilani
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Medical University of Mashhad
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad Universiy of Medical Sciences

Expected recruitment start date

2013-04-13, 1392/01/24

Expected recruitment end date

2013-09-15, 1392/06/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of hemodynamic changes of propofol - ketamine with propofol-fentanyl in induction of anesthesia in smokers

Public title

Comparison of hemodynamic changes following propofol

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: smokers; ASA I-II; 18-60 years old
exclusion criteria: hypertension; coronary artery disease; epilepsy; psychological disease; hepaic and renal disease; addiction; sensitivity to fentanil; ketamin; propofol and atracurium; difficult intubation

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Science

Street address
Vice Chancellor for Research, Mashhad University of Medical Science, Ghoreishi apartment, Daneshgah street

City
Mashhad

Postal code

Approval date
2013-04-13, 1392/01/24

Ethics committee reference number
910962

Health conditions studied

1

Description of health condition studied
Hemodyanmic changes following drug

ICD-10 code
I95.2

ICD-10 code description
Hypotension due to drugs

Primary outcomes

1

Description
Blood pressure changes

Timepoint
Befor induction, befor and after intubation, every five minutes

Method of measurement
Perioperative monitoring

2

Description
Heart rate changes

Timepoint
Befor induction, befor and after intubation, every five minutes

Method of measurement
Perioperative monitoring

Secondary outcomes

1

Description
laryngospasm, salivary secretion increase

Timepoint
After intubation

Method of measurement
Clinical observation

Intervention groups

1

Description
first group: fentanil administration before propofol induction

Category
Prevention

2

Description
second group: ketamin administration before propofol induction

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Emergency Operating Room, Imam Reza Hospital

Full name of responsible person
Mehryar Taghavi Gilani

Street address
Bahar street

City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Mashhad University of Medical Science
Full name of responsible person
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City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Mashhad University of Medical Science
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
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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