

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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

Name of organization / entity

Medical University of Mashhad

Country

Iran (Islamic Republic of)

Phone

+98 51 1852 5209

Email address

taghavim@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University 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; hepatic and renal
disease; addiction; sensitivity to fentanyl; 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

Hemodynamic changes following drug

ICD-10 code

I95.2

ICD-10 code description

Hypotension due to drugs

Primary outcomes

1

Description

Blood pressure changes

Timepoint

Before induction, before and after intubation, every five
minutes

Method of measurement

Perioperative monitoring

2

Description

Heart rate changes

Timepoint

Before induction, before 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: fentanyl 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

Mehryar Taghavi Gilani

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

Imam Reza Hospital

Full name of responsible person

Mehryar Taghavi Gilani

Position

Assistant Professor of Anesthesia

Other areas of specialty/work

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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