

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison of different doses of propofol on hemodynamics symptoms and bispectral index (BIS) in patients undergoing induction of anesthesia

Protocol summary

Summary

This aim of this study is to compare two doses of 1 mg/kg and 2.5 mg/kg propofol on the hemodynamic changes and BIS in patients undergoing anesthesia induction and tracheal intubation. In this double blind clinical trial, both patients and experts of measuring hemodynamic changes and bispectral index haven't any awareness about history of individuals in groups under study, 92 patients referred to educational hospital of Ayatollah Kashani, candidate for surgery undergoing induction of general anesthesia. Their inclusion criteria is, aged 20-80 years old, patients with class I and ASA class II. Their exclusion criteria is any observable unforeseen complications after injection of propofol, patients who have more than class I and ASA class II, and patients with drug sensitivity. They are selected in convenience sampling and are divided in two groups randomly. For induction of anesthesia, the first group uses dose of one mg per kg and the second group receives dose of 2.5 mg per kg propofol. It is used a dose of 3 mg per kg fentanyl for premedication and a half of milligram per kilogram of Atracurium for muscle relaxation and to facilitate intubation. It is evaluated indices of systolic and diastolic blood pressure, average arterial blood pressure, pulse beat and bispectral index in four different time parts (5 minutes before induction, 1 and 5 minutes after induction, and immediately after intubation) by monitoring set and Bispectral index assessment set. The score of myoclonus in 1 minute after induction of anesthesia based on movement score is recorded through observation.

General information

Acronym

Biispectral Index

IRCT registration information

IRCT registration number: **IRCT2015030218099N3**

Registration date: **2015-05-23, 1394/03/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-23, 1394/03/02

Registrant information

Name

Gholamreza Shabanian

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 3333 0061

Email address

gshabanian@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and Technology, Shahrekord University of Medical Sciences

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of different doses of propofol on hemodynamics symptoms and bispectral index (BIS) in patients undergoing induction of anesthesia

Public title

Effect of Propofol on vital signs and assessing the level of anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Aged between 20 and 80 years old, patients under surgery with general Anesthesia, patients with class I and ASA class II. Exclusion criteria: any observable unpredictable complications after injection of propofol; patients with ASA class higher than I and II, patients with drug sensitivity, and patients with contraindications due to the use of this drug.

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **92**

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**

Vice chancellor for research, Shahrekord University of Medical Sciences

Street address

Vice chancellor for research, Shahrekord University of Medical Sciences, Kashani Blvd

City

Shahrekord

Postal code**Approval date**

2012-08-12, 1391/05/22

Ethics committee reference number

18-4-91

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

anesthesia

ICD-10 code

F44.6

ICD-10 code description

Dissociative anaesthesia and sensory loss

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

Movement Score

Timepoint

1 min after the induction of anesthesia

Method of measurement

observation

2**Description**

blood pressure

Timepoint

5 min before induction of anesthesia, 1 min and 5min after induction of anesthesia and after intubation

Method of measurement

monitoring devices

3**Description**

level of consciousness

Timepoint

5 minutes before induction of anesthesia, 1 minute and 5 minutes after intervention and after intubation

Method of measurement

BIS monitoring set

Secondary outcomes

empty

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

In the first interventional group 46 patients receive intravenous propofol in a dose of one mg per kg of weight(Ampoules made in Iran by drug Behestan Co.) for anesthesia induction. Dose of 3 mg per kg fentanyl(Ampoules made in Iran by Aboureyhan Co.) for premedication and a half of milligram per kilogram of Atracurium(Ampoules made in Iran by Caspian Co.) intravenously for muscle relaxation and to facilitate intubation.

Category

Treatment - Drugs

2

Description

In the second interventional group, 46 patients receive intravenous propofol in a dose of 2.5 mg per kg of weight(Ampoules made in Iran by drug Behestan Co.) for anesthesia induction. Dose of 3 mg per kg fentanyl(Ampoules made in Iran by Aboureyhan Co.) for premedication and a half of milligram per kilogram of Atracurium(Ampoules made in Iran by Caspian Co.) intravenously for muscle relaxation and to facilitate intubation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Kashani Hospital

Full name of responsible person

Dr. Gholamreza Shabani

Street address

Department of anesthesiology, Ayatollah Kashani Hospital, Parastar St.

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahrekord University of Medical Sciences

Full name of responsible person

Dr.Mahmoud Mobasheri

Street address

Vice chancellor for research, Shahrekord University of Medical Sciences, Kashani Bld.

City

Shahrekord

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, Shahrekord 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

Shahrekord University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Shabani

Position

Anesthesiologist

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Dr. Gholamreza Shabani

Position

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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