Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 Shabanian
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 Shabanian
Position
Anesthesiologist
Other areas of specialty/work
Street address
Department of anesthesiology, Ayatollah Kashani Hospital, Parastar st.
City
Shahrekord
Postal code
Phone
+98 38 3222 0016
Fax
Email
gshabanian@skums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahrekord University of Medical sciences
Full name of responsible person
Dr. Gholamreza Shabanian
Position
Anesthesiologist
Other areas of specialty/work
Street address
Department of anesthesiology, Ayatollah Kashani Hospital, Parastar St.
City
Shahrekord
Postal code
Phone
+98 38 3222 0016
Fax
Email
gshabanian@skums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shahrekord University of Medical Sciences
Full name of responsible person
dr. Gholamreza Shabanian
Position
Anesthesiologist
Other areas of specialty/work
Street address
Department of anesthesiology, Ayatollah Kashani

Hospital, Parastar St.
City
Shahrekord
Postal code
Phone
+98 38 3222 0016
Fax
Email
gshabanian@skums.ac.ir
Web page address

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