Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of midazolam-fentanyl versus propofol-ketamine sedation for peribulbar nerve block

Protocol summary

Summary

Cataract surgery, a common operation in the elder, is frequently performed under regional anaesthesia.Retrobulbar nerve blocks (RBBs) are unpleasant and painful procedures. Sedation with benzodiazepines, and opiates are most commonly used alone or in combination. Inclusion creteria: ASA 1-3; patients older than 60 yr of age (max 80 yr) undergoing cataract extraction and intraocular lens implantation on an ambulatory surgery. Patients were excluded if: they weighed 150% of their ideal body weight; had ischemic heart disease; had uncontrolled hypertension (systolic/diastolic blood pressure 180/ 110 mm Hg) or had a history of allergy to ketamine, propofol, or local anesthetic drugs; had a history of psychiatric disorders; suffered memory or cognitive dysfunction; had ingested a opoids, tranquilizer or psychoactive drug within 2 wk of surgery. primary outcome are Patient satisfaction and Quality of sedation. patients divided to two groups: Intervention group (group pk): The assigned study drug was administered in the dose of 0.03 mL/kg (maximum 2.5 mL) as a bolus. Additional study drug was then administered in 0.5-mL increments 15 s apart until they were unresponsive to the verbal command “open your eyes.” Hypnotic dose and supplemental dose of the study drug were recorded. If the patient exhibited grimacing and/or extremity movement requiring restraint, further needle insertion was withheld. Supplemental study drug was then administered in 1 mL increments at 10- s intervals until little or no patient movement and/or grimacing occurred with the advancement of the needle.(max dose 5 ml).Control group(group mf):The patients received either 1 microg/kg of fentanyl and 0.02 mg/kg of midazolam by bolus IV injection 1 minute before the administration of a PRBB. At the discretion of the anesthesiologist, intraoperative sedation consisting of 1-mL increments of the study drug or 0.5-mL increments of midazolam (1 mg/mL; maximal dose 2 mg) or fentanyl (50 mg/ mL; maximal dose 2 mL) could be administered to keep the patient comfortable but awake and responsive. This study was undertaken to compare quality of sedation for propofol-ketamine and midazolam-fentanyl sedation during peribulbar nerve block and to compare factors such as cardiopulmonary stability, and patient Satisfaction following sedation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013072911676N2**
Registration date: **2013-10-09, 1392/07/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-10-09, 1392/07/17

Registrant information

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Recruitment status

Recruitment complete

Funding source

Theran University of Medical Sceinces

Expected recruitment start date

2013-08-13, 1392/05/22

Expected recruitment end date
2013-09-28, 1392/07/06
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of midazolam-fentanyl versus propofol-ketamine sedation for peribulbar nerve block

Public title
Effect of midazolam-fentanyl versus propofol-ketamine sedation for peribulbar nerve block
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion creteria: ASA 1-3; patients older than 60 yr of age (max 80 yr) undergoing cataract extraction and intraocular lens implantation on an ambulatory surgery. Patients were excluded if: they weighed 150% of their ideal body weight; had ischemic heart disease; had uncontrolled hypertension (systolic/diastolic blood pressure 180/ 110 mm Hg) or had a history of allergy to ketamine, propofol, or local anesthetic drugs; had a history of psychiatric disorders; suffered memory or cognitive dysfunction; had ingested a opoids, tranquilizer or psychoactive drug within 2 wk of surgery.
Age
From **60 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
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
Eye Research Center of Tehran university medical sceince
Street address
Farabi hospital,Qazvin squer, south karegar
City
Tehran
Postal code
1336616351
Approval date
2013-03-14, 1391/12/24
Ethics committee reference number
irc/s/190

Health conditions studied

1

Description of health condition studied
Sedation in peribulbar block cataract surgery
ICD-10 code
H25.9
ICD-10 code description
Senile cataract, unspecified

Primary outcomes

1

Description
Patient satisfaction
Timepoint
3 to 5 min after injection
Method of measurement
Question

2

Description
Quality of sedation
Timepoint
During injection
Method of measurement
Scale

Secondary outcomes

1

Description
Hemodynamic (systolic, diastolic and mean BP, heart rate)
Timepoint
1 min after sedation and 3 min after injection
Method of measurement
Automated hemodynamic monitoring , electrocardiogram

2

Description
Spo2
Timepoint
1-min after sedation and at 3 min after injection PBB

Method of measurement
Pulse oximeter

3

Description
Degree of respiratory depression
Timepoint
1-min after sedation and at 3 min after injection PBB
Method of measurement
Table of score

4

Description
Air way intervention
Timepoint
1-min after sedation and at 3 min after injection PBB
Method of measurement
Table of score

5

Description
Side effects of drugs
Timepoint
During operation
Method of measurement
Record

Intervention groups

1

Description
Intervention group (group pk): A minidose of lidocaine (10mg) for local anesthesia of the vein endothelium was injected through the Intravenous catheter 1 min before the injection of propofol. The assigned study drug was administered in the dose of 0.03 mL/kg (maximum 2.5 mL) as a bolus. Additional study drug was then administered in 0.5-mL increments 15 s apart until the patients' eyes closed and they were unresponsive to the verbal command "open your eyes." The volume of study drug administered up to this point was termed the "hypnotic dose." Hypnotic dose and supplemental dose of the study drug were recorded. If the patient exhibited grimacing and/or extremity movement requiring restraint, further needle insertion was withheld. Supplemental study drug was then administered in 0.5- to 1 mL increments at 10- s intervals until little or no patient movement and/or grimacing occurred with the advancement of the needle.(max dose 5 ml).
Category
Treatment - Drugs

2

Description
Control group(group mf):The patients received either 1 microg/kg of fentanyl and 0.02 mg/kg of midazolam by bolus IV injection 1 minute before the administration of a PRBB. At the discretion of the anesthesiologist, intraoperative sedation consisting of 1-mL increments of the study drug or 0.5-mL increments of midazolam (1 mg/mL; maximal dose 2 mg) or fentanyl (50 mg/ mL; maximal dose 2 mL) could be administered to keep the patient comfortable but awake and responsive
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Farabi hospital
Full name of responsible person
Abbas ostadalipour, anesthesiologist, assistant professor
Street address
Operation Room Farabi hospital, south karegar
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research, Tehran University of Medical Sciences and Health Services
Full name of responsible person
Dr Akbar Fotouhi
Street address
Building of Vice chancellor for Research, Tehran University of Medical Sciences and Health Services , floor 5, Ghods st. Cross, Keshavarz Bv
City
Tehran
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, Tehran University of Medical Sciences and Health Services
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
Tehran University of Medical Sceinces
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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