

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 criteria: 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 opioids, 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

Name

Abbas Ostadalipour

Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Theran University of Medical Sciences

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 criteria: 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 opioids, 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 science

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 Sciences
Full name of responsible person
Abbas Ostadalipour

Position
Assistant Professor/ Anesthesiologist

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