Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of ketamine-propofol and ketamine-midazolam on the sedation level during cataract surgery by phacoamulsification method

Protocol summary

Study aim

Determination of the Effectiveness of Two Drug Combinations of Ketamine Midazolam and Ketamine Propofol on the sedation level in Patients undergoing Phacoemulsification cataract surgery

Design

Randomised clinical trial, double blinded with a parallel group design of 68 patients candidate for cataract surgery who are randomly divided into two groups based on arandom number table.

Settings and conduct

In this study, two compounds of ketamine-midazolam and ketamine-propofol are used in two groups of cataract patients undergoing phacoemulsification surgery in the Feyz Hospital of Isfahan and the level of sedation is measured in each group.. Patient and researcher are not aware of the type of drug used.Data is also recorded by a person who is not aware of the type of medication used.

Participants/Inclusion and exclusion criteria

Entry conditions include patients who are candidates for cataract surgery and patients who are satisfied with the study. Conditions for not entering are items such as history of allergy or allergic reaction to any of the medication used in the study ; high intraocular pressure or intracranial pressure; cardiovascular risk; advanced epilepsy or history of seizure.

Intervention groups

In the first intervention group 0.5 mg/kg Ketamine with 1 mg/kg propofol is injected. In case of need, 20 mg of ketamine is injected and recorded as a rescue dose and at the end the prescribed total dose is recorded. In the second intervention group 0.05 mg/kg Midazolam with 0.5 mg/kg Ketamine is injected. In case of need, 25 mg of ketamine is injected and recorded as a rescue dose and at the end the prescribed total dose is recorded.

Main outcome variables

Sedation level; Intensity of pain; Arterial blood pressure; Arterial oxygen saturation; Heart rate; Pharmacological complications; Recovery time; Surgeon satisfaction.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170809035601N7**
Registration date: **2018-08-28, 1397/06/06**
Registration timing: **retrospective**

Last update: **2018-08-28, 1397/06/06**
Update count: **0**

Registration date

2018-08-28, 1397/06/06

Registrant information

Name

Hamidreza Shetabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-02, 1396/09/11

Expected recruitment end date

2018-07-20, 1397/04/29

Actual recruitment start date

2017-12-02, 1396/09/11

Actual recruitment end date

2018-07-20, 1397/04/29

Trial completion date

empty

Scientific title

Comparison of the effect of ketamine-propofol and ketamine-midazolam on the sedation level during cataract surgery by phacoamulsification method

Public title

Propofol-Ketamine versus Midazolam-Ketamine for sedation in patients undergoing cataract surgery by phacoamulsification method.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are candidates for cataract surgery. Patients who are satisfied to enter the study. Patients aged 30-88 years.

Exclusion criteria:

History of allergy or allergic reaction to any of the medication used in the study. History of head injuries. High intraocular pressure or intracranial pressure. Cardiovascular risk. Severe respiratory disease. Advanced epilepsy or history of seizure or neurological disorder. The presence of any tumor or brain metastasis. Use of any analgesic and anesthetic drug.

Age

From **30 years** old to **88 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **68**

Actual sample size reached: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

In the operating room, patients are assigned to either midazolam ketamine or propofol ketamine based on a random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and the researcher are not aware of the type of medication used.Medications are prepared by an anesthetic expert who has no role in the study and then injected by an anesthetist to each patient group. The person who records the data is also unaware of the type of medication used.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences and Health Services,Building No. 4, Research and Technology Deputy of University, Hazar Jarib Street

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2017-12-31, 1396/10/10

Ethics committee reference number

IR.MUI.REC.1396.3.629

Health conditions studied

1

Description of health condition studied

Cataract surgery

ICD-10 code

H26.9

ICD-10 code description

Unspecified cataract

Primary outcomes

1

Description

Sedation level

Timepoint

After induction of anesthesia, during the procedure every 5 minutes.

Method of measurement

Modified Ramsay Sedation Scale(RSS)

Secondary outcomes

1

Description

Mean Arterial Pressure

Timepoint

Before the Procedure, During the process every 10 minutes and in recovery every 10 minutes up to two hours.

Method of measurement

pressure gauge

2

Description
Heart rate
Timepoint
Before the Procedure, During the process every 10 minutes and in recovery every 10 minutes up to two hours.
Method of measurement
Pulse oximeter

3

Description
Arterial oxygen saturation
Timepoint
Before the Procedure, During the process every 10 minutes and in recovery every 10 minutes up to two hours.
Method of measurement
Pulse oximeter

4

Description
Intensity of pain
Timepoint
During the process every 10 minutes and in recovery every 10 minutes up to two hours.
Method of measurement
Universal Pain assessment tool

5

Description
Frequency of complications
Timepoint
During the process every 10 minutes and in recovery every 10 minutes up to two hours.
Method of measurement
Adverse drug reaction questionnaire

6

Description
Recovery time
Timepoint
After completing the procedure until the exit from the recovery
Method of measurement
Minute Numbers

7

Description
Surgeon Satisfaction
Timepoint
During the procedure
Method of measurement
Likert scale

Intervention groups

1

Description
Intervention group: 0.5 mg/kg Ketamine with 1 mg/kg propofol in a syringe titre is injected. In case of need, 20 mg of ketamine is injected and recorded as a rescue dose and at the end of the prescribed total dose is recorded.
Category
Treatment - Drugs

2

Description
Intervention group: 0.05 mg/kg Midazolam with 0.5 mg/kg Ketamine in a syringe titre is injected. In case of need, 25 mg of ketamine is injected and recorded as a rescue dose and at the end of the prescribed total dose is recorded.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Feiz hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to

make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available