Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Ketamine versus midazolam as an adjuvant to peribulbar block using single inferonasal injection in patients undergoing vitreoretinal surgery: A randomized controlled trial

Protocol summary

Study aim

Evaluating the role of midazolam and ketamine as adjuvants to the peribulbar block in lengthier ophthalmic procedures such as vitreoretinal surgeries.

Design

Parallel group randomized controlled clinical trial with 1:1:1 allocation ratio.

Settings and conduct

Research Institute of Ophthalmology, Giza, Egypt.

Participants/Inclusion and exclusion criteria

We will include adult (30-65 years-old) male or female patients, indicated for vitreoretinal surgeries (with axial length 20-29 mm), and are American Society of Anesthesiologists (ASA) physical status I or II. We will exclude uncooperative patients, patients who can't lie flat for the duration of the procedure (such as orthopneic patients and those with skeletal problems), and those having coagulopathy or using anticoagulant drugs.

Intervention groups

The trial has three groups. Control group (Group C) includes 31 patients. Each will receive peribulbar anesthesia in the form of 4 ml of lidocaine 2%, 75 units of hyaluronidase, and 4 ml of bupivacaine 0.5% to which 1 ml of normal saline is added. Midazolam group (Group M) includes 31 patients. Each will receive peribulbar anesthesia in the form of 4 ml of lidocaine 2%, 75 units of hyaluronidase, and 4 ml of bupivacaine 0.5% to which 1 mg midazolam is added. Ketamine group (Group K) includes 31 patients. Each will receive peribulbar anesthesia in the form of 4 ml of lidocaine 2%, 75 units of hyaluronidase, and 4 ml of bupivacaine 0.5% to which 25 mg of ketamine is added.

Main outcome variables

Primary outcomes include the onset of globe akinesia and the duration of analgesia. Secondary outcomes include the duration of motor block, the onset of corneal anesthesia, lid akinesia, and the vital data (blood pressure, oxygen saturation, and pulse rate).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201220049777N2**
Registration date: **2021-07-07, 1400/04/16**
Registration timing: **prospective**

Last update: **2021-07-07, 1400/04/16**
Update count: **0**

Registration date

2021-07-07, 1400/04/16

Registrant information

Name

Noha Osama

Name of organization / entity

Research Institute of Ophthalmology

Country

Egypt

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+20 2 35735688

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-15, 1400/04/24

Expected recruitment end date

2021-08-15, 1400/05/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Ketamine versus midazolam as an adjuvant to peribulbar block using single inferonasal injection in patients undergoing vitreoretinal surgery: A randomized controlled trial

Public title

Ketamine versus midazolam as an adjuvant to peribulbar block using single inferonasal injection in patients undergoing vitreoretinal surgery: A randomized controlled trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing vitreoretinal surgeries with axial length 20-29 mm Adults (male or female) aged from 30 to 65 years old American Society of Anesthesiologists (ASA) physical status I or II

Exclusion criteria:

Uncooperative patients Patients who can’t lie flat for the duration of the procedure as those with skeletal problems or orthopneic patients Patients with coagulopathy or using anticoagulant drugs

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **93**

Randomization (investigator's opinion)

Randomized

Randomization description

We will use the sequentially numbered, opaque sealed envelopes method. We will use envelopes that are impermeable to intense light, and the allocation sequence will be concealed from the physicians enrolling and assessing participants. To prevent subversion of the allocation sequence, the name and hospital admission number of the participant will be written on the envelope. Carbon paper will transfer the information onto the allocation card inside the envelope. Corresponding envelopes will be opened only after the enrolled participants complete all baseline assessments and it is time to allocate the intervention.

Blinding (investigator's opinion)

Single blinded

Blinding description

Only participants will be blinded to the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethical Committee of the Research Institute of Ophthalmology

Street address

2 El Ahram Street

City

Giza

Postal code

12557

Approval date

2021-03-14, 1399/12/24

Ethics committee reference number

14-3-2021

Health conditions studied

1

Description of health condition studied

Peribulbar block in adult patients undergoing vitreoretinal surgeries.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The onset of globe akinesia.

Timepoint

At 1, 3, 5 minutes after the block.

Method of measurement

The 3-point scale.

2

Description

The duration of analgesia.

Timepoint

Time from the block till first analgesia required.

Method of measurement

The 10-point Visual Analog Scale.

Secondary outcomes

1

Description

The duration of motor block.

Timepoint
At 1, 2, 3, 4, and 5 h postoperative.
Method of measurement
Clinical assessment of regaining full movement.

2

Description
The onset of lid akinesia.
Timepoint
At 1, 2, and 3 min after the block.
Method of measurement
The 3-point scale.

3

Description
The onset of corneal anesthesia.
Timepoint
At 15 seconds intervals for one minute after the block.
Method of measurement
Clinical assessment using a cotton pad.

4

Description
The vital data (blood pressure, oxygen saturation, and pulse rate).
Timepoint
Before giving the block (baseline) and then every 5 minutes after the block.
Method of measurement
Clinical assessment.

Intervention groups

1

Description
Control group (Group C) received peribulbar anesthesia with a local anesthetic mixture composed of 4 ml of lidocaine 2%, 75 units of hyaluronidase, and 4 ml of bupivacaine 0.5% to which 1 ml of normal saline is added.
Category
Other

2

Description
Midazolam group (Group M) received peribulbar anesthesia with a local anesthetic mixture composed of 4 ml of lidocaine 2%, 75 units of hyaluronidase, and 4 ml of bupivacaine 0.5% to which 1 mg of midazolam is added.
Category
Other

3

Description
Ketamine group (Group K) received peribulbar anesthesia with a local anesthetic mixture composed of 4 ml of lidocaine 2%, 75 units of hyaluronidase, and 4 ml of bupivacaine 0.5% to which 25 mg of ketamine is added.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Research Institute of Ophthalmology
Full name of responsible person
Dr. Noha Osama
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Self-funded
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Research Institute of Ophthalmology
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Dr. Noha Osama
Position
Assistant professor
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Ketamine versus midazolam for peribulbar block in vitreoretinal surgeries IPD set (all collected deidentified IPD).
When the data will become available and for how long
Beginning 12 months and ending 24 months following article publication.
To whom data/document is available
Researchers from academic institutions whose proposal for the use of data has been approved by an independent review committee identified for this purpose.
Under which criteria data/document could be used
For IPD meta-analysis.
From where data/document is obtainable
From the PI.
What processes are involved for a request to access data/document
A proposal for the use of data to be submitted to the PI, then evaluated by an independent review committee identified for this purpose.
Comments