Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

The comparison analgesic effect of fentanyl plus midazolam or fentanyl plus propofol on patients during cataract surgery under peribulbar block: A randomized clinical trial

Protocol summary

Study aim

The aim of this study is to investigate the sedation of fentanyl-midazolam combination with fentanyl-propofol combination after peribulbar block on surgeon and patient satisfaction during cataract surgery.

Design

A randomized clinical trial, with two control groups, with parallel groups, one blind, randomized, phase 3, and on 1116 patients. Random Allocation software was used for randomization.

Settings and conduct

The study is carried out in Amiral Mominin Hospital and Farabi Surgery Clinic (the only private eye surgery referral center in the province) in Rasht. The study is single blind.Injections are performed in the operating room and no patients have no knowledge of the type of intervention, but doctors know the type of anesthetic.

Participants/Inclusion and exclusion criteria

Inclusion criteria: unilateral cataract surgery, patients aged 50-80 years with ASA class I, II, elective surgery, fasting patients, surgeries performed under peribulbar block by an ophthalmologist with more than 25 years of experience. Exclusion criteria: ASA > 3, uncooperative patients, surgeries performed under other blocks or general anesthesia, coagulation disorder, use of antiplatelet drugs, head tremor (Parkinson's), cognitive disorder, Alzheimer's, fear of closed spaces, history of chronic cough, addiction and the history of taking analgesic drugs and allergies to local anesthetic drugs.

Intervention groups

Group 1 receives sedation with fentanyl 0.5g/kg and repeated for 5-10 minutes. After that, they receive midazolam 0.01 mg/kg. In group two, they receive sedation with fentanyl 0.5g/kg and repeat for 5-10 minutes. Also, both groups also receive hyalase.

Main outcome variables

Degree of sedation, pain intensity, heart rate, SpO2 percentage of arterial oxygen saturation. Intraoperative pain, heart rate, blood pressure, and arterial oxygen saturation are monitored regularly at 5-minute intervals.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230111057106N1**
Registration date: **2023-02-23, 1401/12/04**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-23, 1401/12/04**
Update count: **0**

Registration date

2023-02-23, 1401/12/04

Registrant information

Name

Hassan behboudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3323 6886

Email address

behboudi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The comparison analgesic effect of fentanyl plus midazolam or fentanyl plus propofol on patients during cataract surgery under peribulbar block: A randomized clinical trial

Public title
The comparison analgesic effect of fentanyl plus midazolam or fentanyl plus propofol on patients during cataract surgery under peribulbar block
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Unilateral cataract surgery patients aged 50-80 years with ASA class I, II elective surgery fasting patients surgeries performed under peribulbar block by an ophthalmologist with more than 25 years of experience
Exclusion criteria:
ASA > 3 surgeries performed under other blocks or general anesthesia coagulation disorder use of antiplatelet drugs head tremor (Parkinson's) cognitive disorder Alzheimer's fear of closed spaces history of chronic cough addiction and history of use Analgesic drugs allergies to local anesthetic drugs non-cooperative patients
Age
From **50 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **116**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method of this study is based on four random blocks. According to the sample size, 27 random blocks are done through the Random Allocation software, and the patients are divided into two groups A (fentanyl-midazolam) and B (fentanyl - Propofol) based on the list of the sequence of random blocks according to the daily visits and having the inclusion criteria, are randomly assigned.
Blinding (investigator's opinion)
Single blinded
Blinding description
The type of anesthesia is not explained to the patient.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
Shahid Siadaty St., Namju St., Rasht
City
Rasht
Province
Guilan
Postal code
41446-66949
Approval date
2022-12-07, 1401/09/16
Ethics committee reference number
IR.GUMS.REC.1401.453

Health conditions studied

1

Description of health condition studied
catarct
ICD-10 code
H25.2
ICD-10 code description
Age-related cataract, morgagnian type

Primary outcomes

1

Description
Degree of sedation using corrected Ramsay scale(RSS>3)
Timepoint
Every 5 minutes
Method of measurement
Clinical examination

Secondary outcomes

1

Description
Patient satisfaction level
Timepoint
Evaluation of patients' satisfaction using a five-point Likert scale, according to statistics, 33.3 is poor, 33.3-66.6 is average, and 66.6 or higher is good.between the end of surgery and transfer to the ward (recovery time).
Method of measurement
In the study "The comparison analgesic effect of fentanyl

plus midazolam or fentanyl plus propofol on patients during cataract surgery under peribulbar block", the way to set up the secondary variable of patient satisfaction can be a "five-point Likert scale". according to statistics, 33.3 is poor, 33.3-66.6 is average, and 66.6 or higher is good.

2

Description
surgeon satisfaction level
Timepoint
Evaluation of surgen's satisfaction using a five-point Likert scale, according to statistics, 33.3 is poor, 33.3-66.6 is average, and 66.6 or higher is good.between the end of surgery and transfer to the ward (recovery time).
Method of measurement
In the study "The comparison analgesic effect of fentanyl plus midazolam or fentanyl plus propofol on patients during cataract surgery under peribulbar block", the method of setting up the secondary variable of surgeon satisfaction can be a five-point Likert scale. according to statistics, 33.3 is poor, 33.3-66.6 is average, and 66.6 or higher is good.

3

Description
anesthesia complications
Timepoint
Anesthesia complications is evaluated using a five-point Likert scale, according to statistics, 33.3 is poor, 33.3-66.6 is average, and 66.6 or higher is good. The time between the end of surgery and transfer to the ward (recovery time) is recorded
Method of measurement
In the study "The comparison analgesic effect of fentanyl plus midazolam or fentanyl plus propofol on patients during cataract surgery under peribulbar block", the secondary variable of anesthesia complications can be set up using a five-point Likert scale. according to statistics, 33.3 is poor, 33.3-66.6 is average, and 66.6 or higher is good.

4

Description
recovery time
Timepoint
Recovery time is evaluated using a five-point Likert scale, according to statistics, 33.3 is poor, 33.3-66.6 is average, and 66.6 or higher is good. The time between the end of surgery and transfer to the ward (recovery time) is recorded.
Method of measurement
In the study "The comparison analgesic effect of fentanyl plus midazolam or fentanyl plus propofol on patients during cataract surgery under peribulbar block" the secondary variable of recovery time can be "five-point Likert scale". according to statistics, 33.3 is poor, 33.3-66.6 is average, and 66.6 or higher is good.

5

Description
pain intensity
Timepoint
every 5 minutes
Method of measurement
clinical examination

6

Description
heart rate
Timepoint
every 5 minutes
Method of measurement
clinical examination

7

Description
SpO2 percentage of arterial saturation
Timepoint
every 5 minutes
Method of measurement
clinical examination

8

Description
Intraoperative pain
Timepoint
every 5 minutes
Method of measurement
clinical examination

9

Description
Blood pressure
Timepoint
every 5 minutes
Method of measurement
clinical examination

10

Description
arterial blood pressure
Timepoint
every 5 minutes
Method of measurement
clinical examination

Intervention groups

1

Description
Intervention group: The intervention group receives a sedation with fentanyl 0.5g/kg and it is repeated for 5-10 minutes. After that, midazolam 0.01mg/kg - Hyalase patients also receive.

Category
Treatment - Drugs

2

Description
Intervention group: The intervention group received two sedation with fentanyl 0.5g/kg and repeated for 5-10 minutes - patients also received hyalase.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amiralmomenin Hospital, Rasht
Full name of responsible person
Dr Hassan Behboudi
Street address
Eye Research Center, Amiralmomenin Hospital, 17 Shahrivar St, Rasht
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Guilan University Of Medical Sciences
Full name of responsible person
Dr Mohammad Reza Naghipour
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41446-66949
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Email
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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
Guilan 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
Guilan University of Medical Sciences
Full name of responsible person
Dr Hassan behboudi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Ophthalmology
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Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Position

Researcher

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not 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