

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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)

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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

AgeFrom **50 years** old to **80 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant

Sample sizeTarget 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

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Shahid Siadaty St., Namju St., Rasht

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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**

cataract

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.

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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

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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

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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Full name of responsible person

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Position

Associate professor

Latest degree

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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