

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparing the effects of remifentanil with fentanyl on pain intensity, hemodynamic status and post-anesthesia complications of cataract surgery candidate

Protocol summary

Study aim

Comparing the effects of remifentanil with fentanyl on pain intensity, hemodynamic status and post-anesthesia complications of cataract surgery candidate

Design

This study will be conducted as a randomized clinical trial (blocks of four), double-blind, with parallel groups, without a control group, and phase 2-3, with the participation of 80 patients.

Settings and conduct

This study is a randomized clinical trial (blocks of four), double-blind (participants and results analyzer), with parallel groups, without a control group and phase 2-3 and with the participation of 80 ERCP candidates referred to Imam Reza Hospital (Tabriz) will be done.

Participants/Inclusion and exclusion criteria

The criteria for entering the study include: ASA class I and II, candidates for cataract surgery and consent to participate in the study, and the exclusion criteria are: having diabetes or other endocrine disorders and using painkillers in the last 24 hours.

Intervention groups

In the fentanyl group (group B), induction with 1 mg of midazolam, 0.7 micrograms per kilogram of body weight of fentanyl, 1 to 2 mg per kilogram of body weight of propofol along with 1 mg per kilogram of the patient's body weight Lidocaine and finally 10 mg of atracurium will be injected. In the remifentanil group (group A), induction with 1 mg of midazolam, 2 to 4 micrograms per kilogram of body weight of remifentanil, 1 to 2 mg per kilogram of body weight of propofol along with 1 mg per kilogram of body weight Lidocaine will be injected into the patient's body. Then, the speed of the onset of anesthesia and the complications after the surgery will be recorded in recovery.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190325043107N35**

Registration date: **2023-09-01, 1402/06/10**

Registration timing: **prospective**

Last update: **2023-09-01, 1402/06/10**

Update count: **0**

Registration date

2023-09-01, 1402/06/10

Registrant information

Name

Mehdi Khanbabayi Gol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 7054

Email address

khanbabayimehdi69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-20, 1402/06/29

Expected recruitment end date

2023-11-20, 1402/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of remifentanil with fentanyl on pain intensity, hemodynamic status and post-anesthesia complications of cataract surgery candidate

Public title

Effects of remifentanil with fentanyl on pain intensity, hemodynamic status and post-anesthesia complications

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

ASA class I and II Candidate for cataract surgery Consent to participate in the study

Exclusion criteria:

Having diabetes or other endocrine disorders Use of painkillers in the last 24 hours

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, with a sample size of 80, we use the patients using the block permutation randomization method, which is used in this method to balance the number of allocated samples, and with 4 people in each block. We assemble the possible blocks as follows. block 1: BBAA, block 2: AABB, block 3: ABAB, block 4: BABA, block 5: ABBA, and block 6: BAAB, we need 20 blocks for 80 people. It is random in the block method. We choose numbers from one to six. For example, if number 6 is chosen as the first block and number 2 as the second block, the people who enter the study will be given BAABAABB in order from left to right. and finally they were divided into two intervention groups (group A) and control group (group B).

Blinding (investigator's opinion)

Double blinded

Blinding description

The statistical consultant and the patient will be unaware of the type of grouping in this plan; The final results will be delivered to the statistical consultant. Since the statistical consultant and the patients will not be aware of the grouping of the participants; Therefore, they are blind during the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Approval date

2023-08-22, 1402/05/31

Ethics committee reference number

225

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

G89.11

ICD-10 code description

Acute pain due to trauma

Primary outcomes

1

Description

Pain

Timepoint

Once every hour and for six hours after the end of anesthesia

Method of measurement

Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the remifentanil group (group A), induction with 1 mg of midazolam, 2 to 4 micrograms per kilogram of body weight of remifentanil, 1 to 2 mg per kilogram of body weight of propofol along with 1 mg per kilogram of body weight Lidocaine will be injected into

the patient's body. Then, the speed of the onset of anesthesia and the complications after the surgery will be recorded in recovery.

Category

Prevention

2

Description

Control group: In the fentanyl group (group B), induction with 1 mg of midazolam, 0.7 micrograms per kilogram of body weight of fentanyl, 1 to 2 mg per kilogram of body weight of propofol along with 1 mg per kilogram of the patient's body weight Lidocaine and finally 10 mg of atracurium will be injected. Then, the speed of the onset of anesthesia and the complications after the surgery will be recorded in recovery.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Mehdi Nazari

Street address

Imam Reza Hospital, Azadi Ave

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6165665631

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mkhanbabayi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

Street address

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5165665631

Phone

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Email

Ajouyban@hotmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Khanbabayi Gol

Position

MSc in Nursing Education

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Khanbabayi Gol

Position

MSc in Nursing Education

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

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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