Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 2026

Comparing the effectiveness of preoperative injection of Melatonin-Fentanyl and Midazolam-Fentanyl on the amount of anxiety and pain in Cataract surgery under local anesthesia

Protocol summary

Study aim
Comparing the effects of Melatonin-Fentanyl and Midazolam-Fentanyl on pain and anxiety in Cataract

Design
Clinical trial without a control group, with parallel groups, triple-blind, randomized with Random allocation software, phase 2 on 36 patients.

Settings and conduct
This is a triple-blind randomized clinical trial that will be performed on 36 Cataract candidate patients at Feyz Hospital in Isfahan. After the approval of the university ethics committee, if they have inclusion criteria, patients (or their guardians) will be informed about the study and if they consent, they will enter the groups with random assignment. In each group, the desired intervention is applied and the patient's clinical symptoms are recorded. The clinical caregiver evaluating the symptoms is different from the person performing the intervention and does not know the type of intervention. Patients, despite being studied, are not aware of the type of intervention applied and therefore are all blind. Data analysts also do not know the type of intervention applied in each group and are blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: over 18 years old, candidate for cataract surgery under local anesthesia, and informed consent to enter the study. Non-inclusion criteria: suffering from mental illness, deafness, diabetes, allergies, and obesity

Intervention groups
Intervention group A: In this group, before surgery, patients receive a sublingual tablet containing 3 mg of Melatonin and 50 micrograms of Fentanyl injection, and 3 to 5 drops of topical Tetracaine 0.5% are poured on the eyeball in 4 directions.Intervention group B: In this group, patients receive 1 mg of Midazolam and 50 micrograms of Fentanyl injection before surgery, and 3 to 5 drops of 0.5% topical Tetracaine are poured on the eyeball in 4 directions.

Main outcome variables
The amount of sedation; The amount of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160307026950N41**
Registration date: **2022-07-13, 1401/04/22**
Registration timing: **prospective**

Last update: **2022-07-13, 1401/04/22**
Update count: **0**

Registration date
2022-07-13, 1401/04/22

Registrant information

Name
Behzad Nazemroaya
Name of organization / entity
Isfahan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-23, 1401/05/01

Expected recruitment end date
2022-08-23, 1401/06/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effectiveness of preoperative injection of Melatonin-Fentanyl and Midazolam-Fentanyl on the amount of anxiety and pain in Cataract surgery under local anesthesia

Public title
The effect of Melatonin-fentanyl and Midazolam-fentanyl on pain and anxiety in cataract surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 ASA class I, II and III Candidate for Cataract surgery under local anesthesia Ability to answer questions Informed consent for study
Exclusion criteria:
Patients with a history of obstructive sleep apnea Patients treated with psychiatric drugs Patients with autoimmune diseases, diabetes, nystagmus, leukemia and deafness Allergy to the drugs used Use of painkillers in the past week BMI index greater than 35
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done by the simple method in which each patient will be assigned a code using a random number table (Random allocation software) and Patients fall into one of two groups depending on whether these codes are even or odd. This continues until the number of patients in both groups reaches the required number.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This is a triple-blind clinical trial; In this way, before obtaining consent, patients are informed about the study but do not know which group they will be in and therefore are blind. Also, the researcher who records the patient's symptoms is different from the nurse who injects the drug and does not know the type of drug and is blind. Analysts who analyze the data collected during the study also do not know the type of intervention applied in each group and are blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Biomedical Research, Isfahan University of Medical Sciences
Street address
Hezar Jarib
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2022-03-08, 1400/12/17
Ethics committee reference number
IR.MUI.MED.REC.1400.836

Health conditions studied

1

Description of health condition studied
Cataract
ICD-10 code
H25
ICD-10 code description
Age-related cataract

Primary outcomes

1

Description
Pain intensity
Timepoint
Before the intervention, after the intervention, every 10 minutes after the start of the operation until the end of recovery
Method of measurement
Behavioral Pain Scale questionnaire

2

Description
Anxiety amount

Timepoint
Before the intervention, after the intervention, every 10 minutes after the start of the operation until the end of recovery
Method of measurement
Richmond Agitation-Sedation Scale questionnaire

Secondary outcomes

1

Description
Heart Rate
Timepoint
Before the intervention, after the intervention, every 10 minutes after the start of the operation until the end of recovery
Method of measurement
ECG monitoring

2

Description
Blood Pressure
Timepoint
Before the intervention, after the intervention, every 10 minutes after the start of the operation until the end of recovery
Method of measurement
Sphygmomanometer

3

Description
Respiratory Rate
Timepoint
Before the intervention, after the intervention, every 10 minutes after the start of the operation until the end of recovery
Method of measurement
Counts per minute

4

Description
Recovery stay length
Timepoint
From the time of entry to recovery until exit
Method of measurement
Modified Aldrete Score questionnaire

Intervention groups

1

Description
Intervention group A: In this group of patients, after being placed on the surgical bed, they are subjected to cardiac and respiratory monitoring, and an intravenous line is established for drug injection, as well as the measurement criteria are explained to the patient. Then, before the operation, they receive a sublingual tablet containing 3 mg of Melatonin manufactured by Norm Life Company and 50 Micrograms of Fentanyl injection manufactured by Caspin Company. Also, with the help of the surgeon, 3 to 5 drops of topical Tetracaine 0.5% are poured on the eyeball in 4 directions. to be The patient's symptoms are measured and recorded until the end of the operation and then during recovery.
Category
Prevention

2

Description
Intervention group B: In this group of patients, after being placed on the surgical bed, they are subjected to cardiac and respiratory monitoring, and an intravenous line is established for drug injection, as well as the measurement criteria are explained to the patient. Then, before the operation, they receive 1 mg of Midazolam made by Exir and 50 Micrograms of inject able fentanyl made by Caspin, and with the help of the surgeon, 3 to 5 drops of topical Tetracaine 0.5% are poured on the eyeball in 4 directions. The patient's symptoms are measured and recorded until the end of the operation and then during recovery.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Feyz Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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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Position
medical student
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Person responsible for updating data

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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