Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of melatonin and midazolam on preoperative anxiety and intraoperative hemodynamic disorders in patients candidates for cataract surgery

Protocol summary

Study aim
Comparison of Melatonin and Midazolam on preoperative anxiety and intraoperative hemodynamic disorders in patients candidates for cataract surgery.

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 40 patients. The block method will be used for randomization.

Settings and conduct
This study is conducted in Razi Birjand Hospital, South Khorasan Province, Iran. 40 patients are randomly divided into two intervention groups (A-B). Questions related to preoperative spray anxiety will be asked and evaluated by the study administrator.

Participants/Inclusion and exclusion criteria
Our study population is patients who are candidates for cataract surgery, referring to the eye surgery department of Razi Hospital in Birjand city in 2022, who will be operated under general anesthesia. Inclusion criteria will include informed consent, ASA class 1 and 2. Exclusion criteria: drug addiction; lack of cooperation with the study manager; heart failure; uncontrolled blood pressure; use of anticoagulants; use of anti-epileptic drugs; use of immunosuppressive drugs; history of liver or kidney diseases; confusion, dementia, lack of verbal communication, chronic use of narcotics, treatment with barbiturates or antipsychotic drugs; allergies; body mass index below 18.5 or above 30.

Intervention groups
The studied patients, candidates for cataract surgery, who were randomly assigned to one of two groups: the first group receiving melatonin (0.1 mg/kg of melatonin tablets manufactured by ASI Italy) one hour before the operation, the second group receiving midazolam (70-80 micrograms/kg intravenous manufactured by Elixir Pharmaceutical Company) will be given one hour before the operation.

Main outcome variables
Anxiety; hemodynamics of the patient

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190618043934N15**
Registration date: **2022-11-01, 1401/08/10**
Registration timing: **prospective**

Last update: **2022-11-01, 1401/08/10**
Update count: **0**

Registration date
2022-11-01, 1401/08/10

Registrant information
Name
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-11-06, 1401/08/15
Expected recruitment end date
2023-02-04, 1401/11/15
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of melatonin and midazolam on preoperative anxiety and intraoperative hemodynamic disorders in patients candidates for cataract surgery

Public title

Comparison of melatonin and midazolam on preoperative anxiety and intraoperative hemodynamic disorders in cataract surgery patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having informed consent to enter the study ASA class 1 and 2

Exclusion criteria:

Having a drug addiction Failure to cooperate with the study manager Heart failure Uncontrolled blood pressure Anticoagulant use Taking anti-epileptic drugs Taking immunosuppressive drugs History of liver or kidney diseases Confucius Dementia Lack of verbal communication Chronic use of narcotics Treatment with barbiturates or antipsychotic drugs Allergy Body mass index below 18.5 or above 30

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

The placement of people in each group is randomly placed in one of two groups: the first group receiving melatonin (0.1 mg/kg of melatonin tablets manufactured by ESI Italy) (A) one hour before the operation, the second group receiving midazolam (Dose of 80-70 micrograms/kg intravenous manufactured by Elixir Pharmaceutical Company) (B) will also be given one hour before surgery. One of these blocks will be randomly selected and the patients will be divided into one of Two groups A, B. Then randomization will be done for other patients as well.

Blinding (investigator's opinion)

Double blinded

Blinding description

Outcome Evaluator: The study facilitator (medical student) will perform the necessary evaluation without knowing the type of medication received by the patients and will be recorded in a checklist designed for this purpose. Patients: The patients participating in the study are not aware of their group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Birjand University of Medical Sciences, Ghaffari Blvd, Birjand Town

City

Birjand

Province

South Khorasan

Postal code

9717811674

Approval date

2022-01-18, 1400/10/28

Ethics committee reference number

IR.BUMS.REC.1400.324

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

Anxiety

Timepoint

The patient's anxiety will be evaluated before the administration of the medicine in the eye department (2 hours before the operation), before the surgery and before entering the operating room and in the waiting room for the operation in a conscious state (half an hour before the operation) using Beck's anxiety questionnaire.

Method of measurement

Beck Anxiety Questionnaire

2

Description
Hemodynamics of the patient
Timepoint
Hemodynamics of the patients before the operation (2 hours before the operation), during (half an hour after the start of the operation in the operating room) and after the surgery (after the patient is fully awake, 6 hours after the operation) are investigated by the researcher.
Method of measurement
Hemodynamics of patients, including blood pressure before (2 hours before the operation) and after the operation (after the patient is fully awake, 6 hours after the operation) in the ward using a sphygmomanometer and a medical phone by the study manager (medical intern) and counting Heart rate will be obtained using the radial pulse. Also, the monitoring device in the operating room will be used to check the hemodynamics during the operation (half an hour after the start of the operation in the operating room).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group 1 patients will receive melatonin (0.1 mg/kg melatonin tablets manufactured by ASI Italy) one hour before the operation.
Category
Treatment - Drugs

2

Description
Intervention group 2: patients who are candidates for cataract surgery, will receive midazolam (70-80 micrograms/kg IV manufactured by Elixir Pharmaceutical Company) one hour before the operation.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Otorhinolaryngology Clinic, Razi Birjand Hospital
Full name of responsible person
Atefe Sherbaf Yazdi
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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
Birjand 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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Full name of responsible person
Zabihullah Mohaqiq
Position
Student
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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 need to publish individual patient information
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