Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Investigating the effect of oral Melatonin premedication on the quality of sedation and pain scale in Cataract surgery

Protocol summary

Study aim
Investigating the effect of oral Melatonin premedication on the quality of sedation and pain scale in Cataract surgery

Design
A clinical trial with a control group, with parallel groups, three blinded, randomized, phase 2 on 40 patients. random allocation software will be used for randomization.

Settings and conduct
This is a triple-blind randomized clinical trial that will be performed on 40 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, 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, patients receive a sublingual tablet containing 3 mg of melatonin 1 hour before surgery. Intervention group B: In this group, patients receive a placebo pill (which is similar to melatonin in terms of color, smell, and appearance) 1 hour before the operation.

Main outcome variables
intensity of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160307026950N45**
Registration date: **2022-09-10, 1401/06/19**
Registration timing: **prospective**

Last update: **2022-09-10, 1401/06/19**
Update count: **0**

Registration date
2022-09-10, 1401/06/19

Registrant information

Name
Behzad Nazemroaya

Name of organization / entity
Isfahan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2022-11-22, 1401/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of oral Melatonin premedication on the quality of sedation and pain scale in Cataract surgery

Public title
Investigating the sedative effect of Melatonin in Cataract surgery

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 ASA class I, II and III Candidate for Cataract surgery 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
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

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
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
2020-11-30, 1399/09/10

Ethics committee reference number
IR.MUI.MED.REC.1399.768

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
intensity of pain

Timepoint
before the intervention, before the operation, after anesthesia and then every 10 minutes until the end of recovery

Method of measurement
Behavioral Pain Scale questionnaire

Secondary outcomes

1

Description
Heart Rate

Timepoint
before the intervention, before the operation, after anesthesia and then every 10 minutes until the end of recovery

Method of measurement
ECG monitoring

2

Description
Blood Pressure
Timepoint
before the intervention, before the operation, after anesthesia and then every 10 minutes until the end of recovery
Method of measurement
Sphygmomanometer

Intervention groups

1

Description
Intervention group: In this group, patients receive a sublingual tablet containing 3 mg of Melatonin manufactured by Norm Life 1 hour before surgery. After being placed on the surgical bed, he is subjected to cardiac and respiratory monitoring, an intravenous line is established for drug injection, as well as the measurement criteria are explained to the patient. Then the patient is put under anesthesia and the operation begins. The patient's symptoms are measured and recorded until the end of the operation and then during recovery.
Category
Prevention

2

Description
Control group: In this group, patients receive a placebo sublingual tablet 1 hour before surgery. After being placed on the surgical bed, he is 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 the patient is put under anesthesia and the operation begins. The patient's symptoms are measured and recorded until the end of the operation and then during recovery.
Category
Placebo

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
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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