

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effects of melatonin on anxiety and pain scores of patients, intraocular pressure and operating conditions during cataract surgery under topical anesthesia

Protocol summary

Summary

Objective: To evaluate the effects of melatonin premedication on anxiety and pain scores of patients, operating conditions and intraocular pressure during cataract surgery under topical anesthesia. Methods: A randomized controlled trial was carried out at a teaching hospital. Sixty patients were randomly assigned to receive either sublingual melatonin 3 mg (n =30) or placebo (n=30) 60 minutes before surgery. Verbal anxiety scores and verbal pain scores, heart rate, systolic and diastolic blood pressure, intraocular pressure and quality of operative conditions were recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102223051N3**

Registration date: **2011-04-13, 1390/01/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-04-13, 1390/01/24

Registrant information

Name

Marzieh Khezri

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

vice-chancellor for research, Qazvin university of medical sciences and health services

Expected recruitment start date

2009-09-17, 1388/06/26

Expected recruitment end date

2010-06-19, 1389/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of melatonin on anxiety and pain scores of patients, intraocular pressure and operating conditions during cataract surgery under topical anesthesia

Public title

The effects of melatonin on anxiety and pain scores of patients, intraocular pressure and operating conditions during cataract surgery under topical anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age 25–80 years, scheduled for elective cataract surgery with intraocular lens implantation using phacoemulsification under topical anesthesia with an ASA physical status classification I–III. Exclusion criteria: patients with sleep disorders, autoimmune disease, diabetes, depressive disorder or expected compliance problems (known psychiatric disease), epilepsy, leukemia, insufficient pupillary dilation, nystagmus, deafness, allergy to the study drugs, ongoing treatment with hypnotics or psychotropic drugs (including opioids) within a week of admission, daily analgesic treatment, ß

blockers, Coumadin derivatives and those who could not tolerate Shioetz tonometer during IOP measurement.

Age

From **25 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qazvin University of Medical Sciences & Health Services

Street address

Shahid Bahrani Blvd

City

Qazvin

Postal code

Approval date

2009-07-20, 1388/04/29

Ethics committee reference number

28/20/4012

Health conditions studied

1

Description of health condition studied

anxiety

ICD-10 code

Y47

ICD-10 code description

Complications of medical and surgical care

Primary outcomes

1

Description

anxiety

Timepoint

before premedication (T1), sixty minutes after premedication, on arrival in the operating room (T2), during the operation period (T3) and postoperatively

Method of measurement

VAS (verbal anxiety score)

2

Description

intraocular pressure

Timepoint

before premedication (T1), and postoperatively

Method of measurement

Shioetz tonometer

3

Description

pain

Timepoint

before premedication (T1), 60 minutes after premedication, on arrival to the OR (T2), five minutes after the start of surgery (T3), and postoperatively before discharging the patient from the recovery room (T4)

Method of measurement

Verbal pain score

Secondary outcomes

1

Description

arterial blood pressure

Timepoint

before premedication (T1), sixty minutes after premedication, on arrival in the operating room (T2), during the operation period (T3) and postoperatively before discharging the patient from the recovery room (T4)

Method of measurement

noninvasive measurement of blood pressure

2

Description

heart rate

Timepoint

before premedication (T1), sixty minutes after premedication, on arrival in the operating room (T2), during the operation period (T3) and postoperatively before discharging the patient from the recovery room (T4)

Method of measurement

electrocardiogram

Intervention groups

1

Description

sublingual melatonin 3 mg 60 minutes before surgery

Category

Prevention

2

Description

sublingual placebo tablet 60 minutes before surgery

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Booali Hospital

Full name of responsible person

Professor of Anesthesia

Street address

Kosar hospital, Taleghani street

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice-chancellor for research of Qazvin university of medical sciences

Full name of responsible person

Dr. Saeed Assefzadeh

Street address

Shahid Bahrn Blvd

City

Qazvin

Grant name

Grant code / Reference number

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

Yes

Title of funding source

vice-chancellor for research of Qazvin university of medical sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Qazvin university of medical sciences and health services

Full name of responsible person

Dr. Marzieh Beigom Khezri

Position

assistant professor of Anesthesia

Other areas of specialty/work

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Contact

Name of organization / entity

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Position

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Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty
Analytic Code
empty

Data Dictionary
empty