# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Investigating the effect of melatonin administration before blepharoplasty surgery on pain reduction after surgery In the hospital centers of Shiraz University of Medical Sciences in ۱۴۰۴-۱۴۰۵: A randomized controlled clinical trial

## Protocol summary

**Study aim**
Investigating the effect of melatonin administration before blepharoplasty surgery on pain reduction after surgery In the hospital centers of Shiraz University of Medical Sciences in 2026: A randomized controlled clinical trial

**Design**
This is a triple-blind, parallel-design randomized clinical trial. A total of 81 candidates for blepharoplasty will be included. Eligible patients will be equally allocated to three groups (A, B, and C) using block randomization.

**Settings and conduct**
Patients who are candidates for blepharoplasty surgery and present to Shahid Dastghieb Hospital in Shiraz during the study period will be enrolled if they meet the eligibility criteria and will be randomly allocated to intervention and control groups using block randomization. This study will be conducted as a triple-blind trial, meaning that the patients, the researcher, the outcome assessor, and the statistical analyst will be unaware of the intervention type.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Patients with ASA class I or II (American Society of Anesthesiologists classification), patients aged between 18 and 65 years. Exclusion criteria: Surgery duration exceeding 1.5 hours, enlargement of the surgical incision area, and sensitivity (allergy) to the studied drugs.

**Intervention groups**
Intervention group A: Patients in this group receive one 5 mg melatonin tablet the night before surgery and placebo (starch with similar shape and color) on the morning of surgery. Intervention group B: Patients in this group receive placebo the night before surgery and one 5 mg melatonin tablet one hour before the operation. Control group C: Patients in this group receive placebo both the night before surgery and one hour before the operation (double placebo).

**Main outcome variables**
Pain

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20190511043550N6**
Registration date: **2026-06-27, 1405/04/06**
Registration timing: **prospective**

Last update: **2026-06-27, 1405/04/06**
Update count: **0**

**Registration date**
2026-06-27, 1405/04/06

**Registrant information**

**Name**
Ashkan Panah

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 71 3647 4270

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panah@sums.ac.ir

**Recruitment status**
**recruiting**

**Funding source**

**Expected recruitment start date**
2026-07-23, 1405/05/01

**Expected recruitment end date**

2027-03-21, 1406/01/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Investigating the effect of melatonin administration before blepharoplasty surgery on pain reduction after surgery In the hospital centers of Shiraz University of Medical Sciences in ۱۴۰۴-۱۴۰۵: A randomized controlled clinical trial

**Public title**
Effect of Melatonin Administration Before Eyelid Surgery on Reducing Postoperative Pain: A Clinical Study in Shiraz Hospitals

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Patients with ASA grade I or II (American Society of Anesthesiology classification) Patients between 20 and 60 years old Obtaining Informed Consent from the Patient

**Exclusion criteria:**
Surgery duration exceeding 1.5 hours Wider surgical incision Sensitivity to the studied drugs

**Age**
From **20 years** old to **60 years** old

**Gender**
Both

**Phase**
2

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **81**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
In this study, a randomization table with block sizes of 3 and 6 was considered for 81 patients (27 patients per group). A total of 81 eligible patients were randomly assigned to the three study groups in a 1:1:1 ratio, with 27 participants in each group.

**Blinding (investigator's opinion)**
Triple blinded

**Blinding description**
This study is triple-blind, meaning that the patient, the researcher, and the statistical analyst are unaware of the intervention type. Patient coordination and data collection are carried out in collaboration with the surgeon to ensure prevention of bias in the data and to maintain confidentiality.

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee of Shiraz Medical School

**Street address**
3rd Floor, 3rd buiding of the Shiraz Medical School, Zand Blvd.

**City**
Shiraz

**Province**
Fars

**Postal code**
7134844119

**Approval date**
2026-05-03, 1405/02/13

**Ethics committee reference number**
IR.SUMS.MED.REC.1405.040

## Health conditions studied

### 1

**Description of health condition studied**
Blepharoplasty

**ICD-10 code**
H02.83

**ICD-10 code description**
Dermatochalasis of eyelid

## Primary outcomes

### 1

**Description**
Pain

**Timepoint**
at 2, 6, 12 and 24 hours after the operation.

**Method of measurement**
Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention groupA: Patients in this group receive one 5 mg melatonin tablet the night before surgery and placebo (starch with similar shape and color) on the morning of surgery.

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group B: Patients in this group receive placebo the night before surgery and one 5 mg melatonin tablet one hour before the operation.

**Category**

Treatment - Drugs

**3**

**Description**

Control group C: Patients in this group receive placebo both the night before surgery and one hour before the operation (double placebo).

**Category**

Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Shahid Dastgheib Hospital

**Full name of responsible person**

Vahide Emamifar

**Street address**

Hafez Street, Hafeziyeh Intersection.

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Hamid Mohammadi

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7th floor, central building of Shiraz University of Medical Sciences, Vice Chancellor of research, Zand stree

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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**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Vahide Emamifar

**Position**

Anesthesiology resident

**Latest degree**

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## Person responsible for scientific inquiries

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**Position**
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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