Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effects of melatonin tablets and orange blossom water on sleep quality and preoperative anxiety in patients undergoing elective surgery.

Protocol summary

Study aim
Comparison of the effects of melatonin tablets and orange blossom water on sleep quality and preoperative anxiety in patients undergoing elective surgery.

Design
Randomized, double-blind, active-controlled clinical trial with parallel design

Settings and conduct
This study will be conducted in the inpatient and admission departments of these educational and medical centers (Besat, Shahid Beheshti, and Ekbatan). Patients will be included in the study if they meet the inclusion criteria and give informed consent. Their demographic information will be recorded in a questionnaire and divided into three groups: spring orange, melatonin, and placebo.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged 18 to 65 years Candidates for elective (non-emergency) surgery Ability and willingness to participate in the study and complete the questionnaires Exclusion criteria:Patients under 18 years of age or over 65 years Patients candidates for emergency surgery Patients with a history of serious psychiatric disorders (e.g., major depression, bipolar disorder, schizophrenia) that may affect anxiety or sleep quality Patients with known sleep disorders (e.g., sleep apnea, chronic insomnia)

Intervention groups
Melatonin group: The night before surgery, they receive 5 mg of melatonin tablets. Orange blossom extract group: The night before surgery, they receive 15 ml of standard orange blossom extract. Placebo group (control): The night before surgery, they receive a placebo (with a similar appearance and taste).

Main outcome variables
Anxiety- quality of sleep

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251118068036N3**
Registration date: **2026-05-16, 1405/02/26**
Registration timing: **prospective**

Last update: **2026-05-16, 1405/02/26**
Update count: **0**

Registration date
2026-05-16, 1405/02/26

Registrant information

Name
omid ghorbani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 81 3131 0000

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ghorbaniomid213@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-06-06, 1405/03/16

Expected recruitment end date
2027-06-06, 1406/03/16

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effects of melatonin tablets and orange blossom water on sleep quality and preoperative anxiety in patients undergoing elective surgery.

Public title
Comparing the effects of melatonin and orange blossom water on sleep and anxiety in patients before surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients between the ages of 18 and 65 years Candidate for elective (non-emergency) surgery Ability and willingness to participate in the study and complete the questionnaires

Exclusion criteria:
Patients with a history of serious psychiatric disorders (such as major depression, bipolar disorder, schizophrenia) that may affect anxiety or sleep quality. Patients with known sleep disorders (e.g., sleep apnea, chronic insomnia)

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
This study is a three-group, parallel, randomized controlled clinical trial that aims to compare the effects of melatonin tablets and orange blossom water on sleep quality and preoperative anxiety in patients aged 18 to 65 years who are candidates for elective surgery. Convenient sampling will be performed from patients referring to Besat, Shahid Beheshti, and Ekbatan educational and medical centers. The sample size is 105 people (35 people in each group), and the allocation of individuals to three groups of melatonin, orange blossom water, and placebo will be done using a block randomization method and using sealed and coded envelopes. The intervention will be performed the night before surgery; the melatonin group will receive 5 mg of oral melatonin, the orange blossom water group will receive 15 ml of standard industrial orange blossom water, and the control group will receive the same placebo.Data will be collected using a researcher-made checklist, Spielberger Anxiety Questionnaire, and Chen Sleep Quality Questionnaire on the day of admission (before the intervention) and on the morning of the operation. Inclusion criteria include no history of mental illness, no sensitivity to the intervention, no use of sedatives or hypnotics in the past month, and no severe heart, liver, or kidney diseases. The study is conducted with the approval of the Ethics Committee of Hamadan University of Medical Sciences and the license of the relevant medical centers.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study will be conducted in a double-blind manner. Melatonin tablets, orange blossom water, and placebo will be identical in appearance and packaging and will be coded and prepared by someone other than the implementation team. Patients and outcome assessors will be unaware of the type of medication they receive. Allocation of interventions to patients will be done through sealed, coded, and confidential envelopes that will only be opened in emergency cases.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Hamadan University of Medical Sciences

Street address
Shahid Fahmideh St

City
Hamadan

Province
Hamadan

Postal code
6517838678

Approval date
2026-04-18, 1405/01/29

Ethics committee reference number
IR.UMSHA.REC.1405.019

Health conditions studied

1

Description of health condition studied
Comparison of the effects of melatonin tablets and orange blossom water on sleep quality and preoperative anxiety in patients undergoing elective surgery.

ICD-10 code
G47.0

ICD-10 code description
Insomnia

Primary outcomes

1

Description
anxiety
Timepoint
Pre-intervention (day of admission - baseline): First assessment to record the patient's baseline anxiety level.Post-intervention / Pre-operative (morning of surgery): Second assessment to measure changes in anxiety after receiving the intervention.
Method of measurement
Patient completion of the STAI questionnaire.This questionnaire consists of 40 questions divided into two subscales: overt anxiety (current situation) and covert anxiety (personal trait).Responses are based on a 4-point Likert scale (very low, low, high, very high).Scoring involves weighting the responses (1 to 4) and, in some statements, reverse scoring.The final overall anxiety score is calculated in the range of 20 to 80.

Secondary outcomes

1

Description
Need for sleep aids or sedatives after surgery
Timepoint
Postoperative: Record whether the patient required any adjunctive medications (such as benzodiazepines or other hypnotics) after surgery.
Method of measurement
Through the patient's medical record or direct questioning of the patient/healthcare staff

Intervention groups

1

Description
Intervention group: Melatonin group (first intervention group): Intervention: Taking one 5 mg melatonin tablet orally. Time of administration: The night before surgery. Administration method: The drug is administered in identical packaging and coded by the researcher and under direct supervision to prevent bias.
Category
Treatment - Drugs

2

Description
Intervention group: Orange juice group (second intervention group):Intervention: Consumption of 15 ml of industrialized and standardized orange juice.Time of consumption: The night before surgery.Method of administration: The drug is administered in identical and coded packaging by the researcher and under direct supervision to prevent bias.
Category
Treatment - Drugs

3

Description
Control group: Placebo administration: The placebo is designed to look, taste (as much as possible) and be packaged similarly to melatonin tablets so that it is not visually or sensory different from the original drug. Time of administration: The night before surgery. Method of administration: The drug is administered in a similar, coded packaging by the researcher and under direct supervision to avoid bias.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Mohsen Zarei
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Shahid Fahmideh St
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2

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
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3

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

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
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Alireza Soltanian
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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
Hamedan 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
Hamedan University of Medical Sciences
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Position
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Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Access to data will be available immediately after the final article is published.

When the data will become available and for how long

Access to data will be available immediately after the final article is published

To whom data/document is available

All researchers, researchers and clinical experts will be allowed to access the data of this study.

Under which criteria data/document could be used

It will be welcomed to conduct extensive analysis on the data of this study along with the data of other studies to write meta-analysis review articles.

From where data/document is obtainable

For more information, send an email to Dr. Mohsen Zarei. All correspondence will be addressed to DR.MOHSENZAREI1206@GMAIL.COM.

What processes are involved for a request to access data/document

After making a phone call and submitting a request via email, a final response will be sent within at least 1 month.

Comments