

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

comparison of the effect of melatonin and zolpidem on the onset and number of sleep hours after laparoscopic abdominal surgery

Protocol summary

Study aim

Comparison of the effect of melatonin and zolpidem at the beginning and hours of sleep after laparoscopic abdominal surgery.

Design

Clinical trial, with parallel groups, double-blind, simple randomized, phase 4, on 168 patients who underwent laparoscopic abdominal surgery in affiliated hospitals of Islamic Azad University of Tehran.

Settings and conduct

The subjects to be studied will be selected from among the patients who undergo laparoscopic abdominal surgery in the affiliated hospitals of Tehran Islamic Azad University in 1402 and who meet the inclusion criteria so that the sample size reaches the desired number. Then the patients are divided into three simple random double-blind groups, which are matched in terms of age and gender.

Participants/Inclusion and exclusion criteria

156 patients undergoing laparoscopic abdominal surgery with general anesthesia class ASA 1, 2 referred to Islamic Azad University hospitals in 2011 Inclusion criteria 1. Age between 20 and 50 years 2. Anesthesia class ASA1,2 4. Consent to participate in the study 5. Male gender 6. Laparoscopic abdominal surgery 7. The duration of surgery is less than one hour Exclusion criteria 1. Emergency surgery 2. Pregnant women or possibility of pregnancy 3. Diabetic, cardiac, pulmonary and neurological patients 4. Having a history of sleep disorders

Intervention groups

Intervention group 1: In this group, patients who have undergone laparoscopic abdominal surgery will receive melatonin. Intervention group two: In this group, patients who underwent laparoscopic abdominal surgery will receive zolpidem.

Main outcome variables

Start and number of hours of sleep

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221015056176N1**

Registration date: **2023-08-12, 1402/05/21**

Registration timing: **prospective**

Last update: **2023-08-12, 1402/05/21**

Update count: **0**

Registration date

2023-08-12, 1402/05/21

Registrant information

Name

Farnoosh Javadimarand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2249 4967

Email address

farnooshjavadii@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-19, 1402/05/28

Expected recruitment end date

2023-10-20, 1402/07/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effect of melatonin and zolpidem on the onset and number of sleep hours after laparoscopic abdominal surgery		Tehran Islamic Azad University of Medical Sciences, Khaghani St, Shariati Ave	
Public title	Investigating the effect of melatonin and zolpidem on postoperative sleep disturbance	City	Tehran
Purpose	Treatment	Province	Tehran
Inclusion/Exclusion criteria		Postal code	19499160112
Inclusion criteria:	Age between 20 and 50 years Anesthesia class ASA1,2 Consent to participate in the study Male gender Laparoscopic abdominal surgery The duration of surgery is less than one hour	Approval date	2022-12-26, 1401/10/05
Exclusion criteria:	Emergency surgery Pregnant women or the possibility of pregnancy Diabetic, cardiac, pulmonary and neurological patients Having a history of sleep disorders	Ethics committee reference number	IR.IAU.TMU.REC.1401.327
Age	From 20 years old to 50 years old	Health conditions studied	
Gender	Male	1	
Phase	4	Description of health condition studied	
Groups that have been masked	- Participant - Investigator	Sleep quality after laparoscopic abdominal surgery	
Sample size	Target sample size: 168	ICD-10 code	
Randomization (investigator's opinion)	Not randomized	G47	
Randomization description		ICD-10 code description	
Blinding (investigator's opinion)	Double blinded	Sleep disorders	
Blinding description	The participants in three groups and the researcher remain unaware of how the type of drug is allocated during the study. The patient is informed that there are three types of drug packages in a study and they will receive one of them randomly. they are similar in packaging and have no difference.	Primary outcomes	
Placebo	Used	1	
Assignment	Parallel	Description	
Other design features		Sleep duration score based on Pittsburgh sleep quality index questionnaire	
Secondary Ids	empty	Timepoint	
Ethics committees		Measuring the sleep duration score according to the Pittsburgh sleep quality index questionnaire on the first, second and third nights after surgery	
1		Method of measurement	
Ethics committee		Patient statements in the Pittsburgh Sleep Quality Index Questionnaire	
Name of ethics committee	Research Ethics Committees of Tehran Islamic Azad University Of Medical Sciences	2	
Street address		Description	
		Sleep onset delay score based on the Pittsburgh Sleep Quality Index questionnaire	
		Timepoint	
		Measuring sleep onset delay according to the Pittsburgh sleep quality index questionnaire on the first, second and third night after surgery	
		Method of measurement	
		Patient statements in the Pittsburgh Sleep Quality Index Questionnaire	
		Secondary outcomes	
		empty	
		Intervention groups	
		1	
		Description	
		Intervention group: Patients who undergo laparoscopic	

abdominal surgery receive 10 mg zolpidem for 3 nights after surgery.

Category

Treatment - Drugs

2

Description

Intervention group: Patients who undergo laparoscopic abdominal surgery receive 6 mg of melatonin orally for 3 nights after surgery.

Category

Treatment - Drugs

3

Description

Control group: Patients who undergo laparoscopic abdominal surgery receive a placebo with the same appearance as the drugs of the intervention group for 3 nights after the surgery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Booali hospital

Full name of responsible person

Seyed Hosein Yahyavi

Street address

Booali Hospital, Damavand St., Imam Hossein Square

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Province

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booali.hospital96@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Farshad Hashemian

Street address

Tehran Islamic Azad University of Medical Sciences ,
Khaghani St, Shariati Ave Tehran

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1916893813

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Grant name

Grant code / Reference number

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

No

Title of funding source

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Seyed Hosein Yahyavi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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 are currently no plans to publish.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available