

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effect of sublingual melatonin on the use of opioids used in patients undergoing laparotomy admitted to the ICU

Protocol summary

Study aim

Investigating the effect of sublingual melatonin on the amount of narcotics used in laparotomy patients hospitalized in the ward

Design

This is a clinical trial study with parallel groups, double-blinded randomized, will be conducted on 30 patients undergoing laparotomy admitted to the ICU. Assignment of patients to the study groups will be done by generation of random-numbers table and using computer and excel software.

Settings and conduct

This controlled study is performed on laparotomy patients hospitalized in the ICU. At least 60 patients are randomly assigned to one of the two intervention groups. Patients and researchers will not know about the type of treatment and patient grouping, and thus, this study will remain double-blind until the end of the work.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age older than 18 years, patients who need hospitalization in the intensive care unit for more than 48 hours due to laparotomy surgery; Exclusion from the study: presence of liver failure (liver enzyme more than three times the normal limit), kidney failure (GFR<60), history of brain tumor, history of sensitivity to melatonin.

Intervention groups

Patients in the first group (intervention) will receive 5 mg of sublingual melatonin tablets every night upon entering the intensive care unit, and patients in the second group (control) will receive a placebo drug with the same shape and appearance as melatonin at 9:00 p.m. . The administration of medicine or placebo continues for 7 days in patients in the intensive care unit.

Main outcome variables

The amount of need to receive opioids, the amount of need to receive antibiotics, changes in pain level, possible side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220807055631N1**

Registration date: **2022-08-30, 1401/06/08**

Registration timing: **prospective**

Last update: **2022-08-30, 1401/06/08**

Update count: **0**

Registration date

2022-08-30, 1401/06/08

Registrant information

Name

Negin Ayoubzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3001 3374

Email address

neginayoubzadeh@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sublingual melatonin on the use of opioids used in patients undergoing laparotomy admitted to the ICU		intervention (receiving melatonin or placebo) and evaluation of patients is done by a doctor who does not know about the patient's grouping. The statistical analyzer of the results will not know about the patient grouping	
Public title	Effect of melatonin on opioids used in patients undergoing laparotomy	Placebo	Used
Purpose	Prevention	Assignment	Parallel
Inclusion/Exclusion criteria	Inclusion criteria: Patients older than 18 years Patients undergoing laparotomy surgery requiring hospitalization in the intensive care unit for more than 48 hours Exclusion criteria: Presence of liver failure (liver enzyme more than three times the normal limit) Renal failure (GFR<60) History of brain tumor History of sensitivity to melatonin	Other design features	
Age	From 18 years old	Secondary Ids	
Gender	Both	empty	
Phase	3	Ethics committees	
Groups that have been masked	- Participant - Investigator - Outcome assessor - Data analyser	1	
Sample size	Target sample size: 60	Ethics committee	
Randomization (investigator's opinion)	Randomized	Name of ethics committee	
Randomization description	Patients will be assigned into two groups by simple randomization method. Allocation of patients to the study groups will be done by random numbers generation and using computer by excel software. Random numbers will be generated in Excel with RAND function [(=RAND()*(30))] and with this function 60 random numbers will be created in the range of 1 to 60 in a column. Each patient will be assigned a two-digit code from 01 to 60. From the beginning of the first row, move down the column of random numbers and check the first two digits of the random numbers. The first 30 people seen in our code range will be placed in the first group and the second 30 people will place in the second group. A person from hospital staff, who will not responsible for patient selection, enrollment, or treatment allocation, performs the randomization. The implementation of the random allocation sequence occurs without knowledge of which patient will receive which treatment.	Ethics committee of Golestan Hospital of Jondi Shapoor of Ahwaz University of Medical Sciences	
Blinding (investigator's opinion)	Double blinded	Street address	
Blinding description	In this study, doctors, nurses, those responsible for data collection and those who evaluate the results will be blinded. The appearance of the placebo is similar to the melatonin pill, and the preparation of the drugs is done by the nurse away from the eyes of the patients. Also,	Golestan Ave., farvardin St.	
		City	
		Ahwaz	
		Province	
		Khouzestan	
		Postal code	
		6133333333	
		Approval date	
		2022-05-28, 1401/03/07	
		Ethics committee reference number	
		IR.AJUMS.HGOLESTAN.REC.1401.043	
		Health conditions studied	
		1	
		Description of health condition studied	
		Appendicitis	
		ICD-10 code	
		K37	
		ICD-10 code description	
		Unspecified appendicitis	
		Primary outcomes	
		1	
		Description	
		The need to receive opioids	
		Timepoint	
		daily during ICU stay	
		Method of measurement	
		The need for narcotics (and drug dosage) based on the severity of the patient's pain and the doctor's diagnosis	
		2	
		Description	

The need to receive antibiotics
Timepoint
daily during ICU stay
Method of measurement
Prescribing antibiotics based on doctor's diagnosis

3

Description
Changes in the amount of pain
Timepoint
daily during ICU stay
Method of measurement
based on visual analog scale (VAS)

4

Description
Possible side effects
Timepoint
During ICU stay
Method of measurement
Based on the patient's examination and symptoms

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients will receive 5 mg of sublingual melatonin tablets (the company...) at 9:00 p.m. every night upon entering the intensive care unit. Medication prescription for 7 days in patients in the intensive care unit. continues.
Category
Prevention

2

Description
Control group: Patients will receive a placebo pill with the same shape and appearance as melatonin at 9:00 PM every night upon entering the intensive care unit. Placebo administration continues for 7 days in patients in the intensive care unit.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Negin Ayoubzadeh
Street address
Imam Khomeini Hospital, Azadegan St.

City
Ahvaz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr Mehrnoosh Zakerkish
Street address
Azadegan St.
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Ahvaz
Province
Khouzestan
Postal code
6133333333
Phone
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Email
Zakerkish-m@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Negin Ayoubzadeh
Position
Resident
Latest degree
Medical doctor

Other areas of specialty/work

Anesthesiology

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Full name of responsible person

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Publishing as an article

When the data will become available and for how long

always

To whom data/document is available

All researchers

Under which criteria data/document could be used

To be presented in scientific texts under conditions of confidentiality and copyright

From where data/document is obtainable

Dr Negin Ayoubzadeh

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

Email to the responsible person

Comments