

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of melatonin versus placebo on post-appendectomy pain

Protocol summary

Study aim

To determine the efficacy and safety of melatonin versus placebo for the prevention of post-appendectomy pain

Design

Phase III double-blind randomized placebo-controlled trial with parallel groups on 64 patients, randomization performed using a randomization table generated by the Random Allocation software

Settings and conduct

This study will be performed on 64 candidates of appendectomy under general anesthesia referred to Shahid Mohammadi hospital, Bandar Abbas. Patients will be randomized into two groups based on a randomization table. In the intervention group, 1 hour before surgery, the patients will receive 6 mg oral melatonin and in the control group, the patients will receive placebo. Then, all patients will undergo general anesthesia by an anesthesiologist blinded to patient grouping. After surgery, the awake patients will be transferred to the recovery unit. There the patients will be assessed and in case of visual analogue scale (VAS) pain of >3, 25 mg pethidine will be administered and recorded in the questionnaire. At 2, 12, and 24 hours after surgery, the 10-score VAS will be used for pain assessment and any analgesic requirement will be noted. Patients' sedation will also be evaluated using the Ramsay Sedation Scale (RSS). Given the use of placebo with the same color and form of melatonin, the patients, the care givers, the anesthesiologist, and the assessor will be blinded to the received drug and the study will be double-blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age of 18-80 years, ASA class I & II, candidacy for appendectomy under general anesthesia
Exclusion criteria: addiction, neurological and psychiatric diseases, allergy to melatonin, history of taking analgesics for other reasons

Intervention groups

Intervention group: 6 mg oral melatonin 1 hour before surgery
Control group: placebo 1 hour before surgery

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220507054763N1**

Registration date: **2022-07-13, 1401/04/22**

Registration timing: **retrospective**

Last update: **2022-07-13, 1401/04/22**

Update count: **0**

Registration date

2022-07-13, 1401/04/22

Registrant information

Name

Alireza Abdollahzadeh Baghaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3371 0370

Email address

bagha_ar@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

2018-11-22, 1397/09/01

Actual recruitment end date

2019-11-22, 1398/09/01

Trial completion date

2019-11-22, 1398/09/01

Scientific title

The effect of melatonin versus placebo on post-appendectomy pain

Public title

The effect of melatonin on post-appendectomy pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18-80 years ASA class I & II Candidacy for appendectomy under general anesthesia

Exclusion criteria:

Addiction Allergy to melatonin Neurological or psychiatric disease History of taking analgesics for other reasons

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **64**

Actual sample size reached: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomized into two groups using simple randomization with individuals as the unit of randomization and a randomization table produced by the Random Allocation software. Allocation concealment will be done using unclear envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients in the control group will receive placebo in the same color and form of melatonin. Given that placebo is prepared by the pharmaceutical company which is uninvolved in the study, the patients, the care givers, and the anesthesiologist will be unaware of the received intervention. Also, post-appendectomy pain will be assessed by the patients (blinded to the type of intervention) and sedation will be assessed by the anesthesiologist (the assessor who is blinded to the patient grouping).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hormozgan University of Medical Sciences

Street address

Imam Hossein Blvd., across from Kargaran Sports Complex, Faculty of Medicine

City

Bandar Abbas

Province

Hormozgan

Postal code

7916613885

Approval date

2018-10-14, 1397/07/22

Ethics committee reference number

IR.HUMS.REC.1397.203

Health conditions studied

1

Description of health condition studied

Post-appendectomy pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

Post-appendectomy pain

Timepoint

At 2, 12, and 24 hours after surgery

Method of measurement

Visual analogue scale

Secondary outcomes

1

Description

The amount of analgesics required

Timepoint

Up to 24 hours after surgery

Method of measurement

gr pethidine

2

Description

Sedation

Timepoint

At 2, 12, and 24 hours after surgery

Method of measurement

Ramsay Sedation Scale (RSS)

3

Description

Side effects, including hypotension, bradycardia, and respiratory depression

Timepoint

Up to 24 hours after surgery

Method of measurement

Measurement of blood pressure (systolic blood pressure <90 mmHg), heart beat (<60), and respiratory rate (<12)

Intervention groups

1

Description

Intervention group: One hour before surgery, two 3 mg melatonin tablets (a total of 6 mg) manufactured by Vitans Nature, USA

Category

Prevention

2

Description

Control group: One hour before surgery, two 3 mg placebo tablets (a total of 6 mg) manufactured by Vitans Nature, USA

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohammadi Hospital

Full name of responsible person

Alireza Abdollahzadeh Baghaei

Street address

Jomhuri Eslami Blvd., Shahid Mohammadi Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellery for Research Hormozgan University of Medical Sciences

Full name of responsible person

Teamur Aghamolaei

Street address

Imam Hossein Blvd., across from Kargar Sports Complex

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<https://resv.hums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-Chancellery for Research Hormozgan 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Alireza Abdollahzadeh Baghaei

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Latest degree

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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 is no further information.

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