

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Effect of preoperative sub-lingual melatonin on postoperative pain of patients undergoing colorectal surgery

Protocol summary

Study aim

The effect of preoperative sublingual melatonin on postoperative pain severity in patients undergoing colorectal surgery

Design

Double-blind, Randomized, Placebo-controlled, Two Parallel-Group Trial (Intervention group 30 and control group 30)

Settings and conduct

Department of Surgery, Ghaem Hospital, Mashhad University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion: The patient is a candidate for colorectal surgery; ASA Classification of 1 and 2; Give informed, voluntary and written consent; the patient has not used any narcotic drugs before surgery. Exclusion: a history of alcohol or drug abuse; a history of Seizure; a history of diabetes

Intervention groups

Intervention group: 6 mg melatonin sublingual one hour before surgery Control group: 6 mg placebo sublingual one hour before surgery

Main outcome variables

Postoperative pain severity by Verbal rating scale (VRS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190811044506N1**

Registration date: **2019-08-31, 1398/06/09**

Registration timing: **prospective**

Last update: **2019-08-31, 1398/06/09**

Update count: **0**

Registration date

2019-08-31, 1398/06/09

Registrant information

Name

Maryam Shakiba

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3601 5168

Email address

shakibam961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of preoperative sub-lingual melatonin on postoperative pain of patients undergoing colorectal surgery

Public title

The effect of melatonin on the severity of postoperative pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patient is a candidate for colorectal surgery. ASA Classification of 1 and 2 Give informed, voluntary and written consent Have not used any narcotic drugs before surgery.

Exclusion criteria:

a history of alcohol or drug abuse a history of Seizure a history of diabetes

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with inclusion criteria were divided into control and intervention groups using random numbers table by simple randomization method.

Blinding (investigator's opinion)

Double blinded

Blinding description

The subjects were randomly divided into intervention and control groups after receiving written and informed consent so that they were unaware of their assigned group. The original drug and placebo, which are similar in shape, color and size, are delivered to the patient by the unconscious clinical caregiver.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

Vakilabad Blvd, School of Medicine

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2019-04-30, 1398/02/10

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.149

Health conditions studied**1****Description of health condition studied**

postoperative pain

ICD-10 code

T81

ICD-10 code description

Complications of procedures, not elsewhere classified

2**Description of health condition studied**

abdominal pain

ICD-10 code

R10

ICD-10 code description

Abdominal and pelvic pain

Primary outcomes**1****Description**

Postoperative pain severity

Timepoint

0, 2, 6, 12 and 24 hours after surgery

Method of measurement

Verbal rating scale

Secondary outcomes**1****Description**

sedation

Timepoint

6, 12 and 24 hours after surgery

Method of measurement

Ramsay sedation score

Intervention groups**1****Description**

Intervention group: 6 mg melatonin sublingual one hour before surgery

Category

Treatment - Drugs

2**Description**

Control group: 6 mg placebo sublingual one hour before surgery

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital, Mashhad University of Medical Sciences

Full name of responsible person

Maryam Shakiba

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Ahmad Abad Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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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

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Maryam Shakiba

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

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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

Not applicable

Data Dictionary

Not applicable