Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of preoperative administration of the oral melatonin on postoperative pain in lumbar spinal surgeries

Protocol summary

Study aim
Based on recent studies suggesting the effectiveness of melatonin on postoperative pain and the urgent need for a treatment to reduce pain in patients after surgery. On the other hand due to the lack of similar studies in our country, we aim to conduct this study.

Design
A concealed, randomized, blinded, third phase controlled clinical trial with a parallel group design of 46 patients, enrolled between April and May 2022.

Settings and conduct
Patients who undergo elective spinal surgery in Imam Khomeini Hospital in Tehran are included in the study and one hour before the operation, the first group is given 5 mg of oral melatonin and the second group is given a placebo. After surgery at 1, 2, 6, 12 and 24 hours after surgery, patients' pain intensity was measured using VAS Patients were randomly assigned to treatment groups. None of the patients, researchers, or physicians evaluating the outcome were aware of the type of treatment.

Participants/Inclusion and exclusion criteria
Patients who undergo elective lumbar spinal surgery are included in the study. Exclusion criteria include non-elective surgery, coagulative disorders, kidney or liver failure, opioid abuse, use of any other analgesics, taking medications interfere with melatonin, history of drug allergy to melatonin.

Intervention groups
Patients are divided into two groups. One hour before surgery, the first group receives 5 mg of oral melatonin and the second group receives placebo.

Main outcome variables
Severity of post operative pain based on Visual Analogue Scale(VAS)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220613055157N1**
Registration date: **2022-06-19, 1401/03/29**
Registration timing: **retrospective**

Last update: **2022-06-19, 1401/03/29**
Update count: **0**

Registration date
2022-06-19, 1401/03/29

Registrant information

Name
Mohamadreza Sedighidarijani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2212 7610

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-20, 1400/12/01

Expected recruitment end date
2022-03-20, 1400/12/29

Actual recruitment start date
2022-04-21, 1401/02/01

Actual recruitment end date
2022-05-21, 1401/02/31

Trial completion date
2022-05-21, 1401/02/31

Scientific title
Evaluation of preoperative administration of the oral melatonin on postoperative pain in lumbar spinal surgeries

Public title
The effect of melatonin on postoperative pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Satisfaction for participation in the study candidates for lumbar spinal surgeries
Exclusion criteria:
Lack of cooperation in the study Opioid abuse Use of any other sedatives Taking drugs that interfere with melatonin non-elective surgery coagulative disorders kidney or liver failure history of drug allergy to melatonin
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Actual sample size reached: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, we use block randomization method, a subtype of the restricted randomization. Blocking is usually used for balance in the number of samples assigned to each study group. This feature helps researchers to have equal numbers of samples assigned to each of the case groups when the intermediate analyzes are required during the sampling process. The size of all the blocks is equal and in this RCT we used two-group trial of 6 blocks (including 3 participants in the intervention group and 3 participants in the placebo group). Random allocation software are used as randomization tools. Random sequence generation software in addition to simple randomization capable generates random sequences by block generation method. For hiding, we used allocation concealment. A method for random sequencing of the study participants in a way that before the individual is assigned, the assigned group is not specified. By using sequentially numbered, sealed, opaque envelopes in which the created random sequences are registered on a card. The cards are placed in the envelopes in order. To maintain a random sequence, also on the outer surface of the envelope. The numbering is done in the same way. Finally the envelope are pasted and placed in a box, respectively. At time to start registration of participants, based on the order of entry of the eligible applicants. One of the envelopes is opened in order and the assigned group of the participant will be revealed
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, participants (patients) as well as the researcher and outcome assessor(one person has the both latter roles) are blind. The patient is unaware that he is taking the drug or placebo exactly. The lead researcher, who also evaluats the outcome of the study, similarly do not know which patient receives either the medication or the placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Imam Khomeini Hospital Complex- Tehran University of Medical Sciences
Street address
Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱
Approval date
2021-10-06, 1400/07/14
Ethics committee reference number
IR.TUMS.IKHC.REC.1400.269

Health conditions studied

1

Description of health condition studied
lumbar spine surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Severity of post operative pain based on Visual Analogue Scale(VAS)
Timepoint
Measurement of pain severity at 1, 2, 6, 12 and 24 hours after surgery
Method of measurement
Visual Analogue Scale(VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 5 mg of oral melatonin one hour before surgery
Category
Treatment - Drugs

2

Description
Control group: Control group: placebo one hour before surgery
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
Mohammad reza Sedighi
Street address
Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran
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Web page address
https://ikhc.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotouhi
Street address
Central Building of Tehran University of Medical Sciences, Qods st., Keshavarz Blvd.
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Phone
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Email
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Web page address
https://vcr.tums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
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Position
intern
Latest degree
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Other areas of specialty/work
General Practitioner
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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
Undecided - It is not yet known if there will be a plan to make this available

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