Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation the effects of different doses of Melatonin on pain control after surgery and their effects on the need for opioid and non-opioid analgesics in patients who are candidates for spinal anesthesia: a double-blind clinical trial

Protocol summary

Study aim

evaluating the effect of oral melatonin in postoperative pain control and its effect on the need for opioid and non-opioid analgesics.

Design

A randomized, double-blind, parallel-group, controlled, phase 3 clinical trial on 152 patients. For randomization, eight random block permutations method was used.

Settings and conduct

The location of this study is Apadana Hospital in Ahvaz and Patients who meet the conditions for entering the study are randomly divided into 4 groups, including group A with a dose of 3 mg of melatonin, group B with a dose of 10 mg of melatonin, group C with a dose of 20 mg of melatonin, and group D with a control group. After obtaining written consent from the patients, half an hour before the start of spinal anesthesia, the drug or placebo (a placebo similar to the drug in terms of size and appearance) is given to the patients. From the time of receiving the drug until 24 hours after the end of Surgery, patients are regularly monitored.

Participants/Inclusion and exclusion criteria

Entry conditions: 1. Be over 18 years old. 2. Candidate patients for spinal anesthesia 3. Completing the informed consent form Exclusion conditions: 1. Patients with liver failure (liver enzymes more than 3 times the normal limit) 2. Patients with kidney failure (GFR<60) 3. Pregnancy 4. Patients with brain tumors. 5. Patients who have a history of neurological and psychological diseases. 6. People who take warfarin. 7. Drug abuse 8. History of sensitivity to melatonin 9. The patient's unwillingness to continue participating in the study at any time

Intervention groups

4 intervention groups including the first group with a dose of 3 mg of melatonin, the second group with a dose of 10 mg of melatonin, the third group with a dose of 20 mg of melatonin, and the fourth group with a control group

Main outcome variables

Pain intensity and the amount of opioid and non-opioid drugs used

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230516058207N1**
Registration date: **2023-06-13, 1402/03/23**
Registration timing: **prospective**

Last update: **2023-06-13, 1402/03/23**
Update count: **0**

Registration date

2023-06-13, 1402/03/23

Registrant information

Name

Iman Abdolkhani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-26, 1402/04/05

Expected recruitment end date

2023-10-27, 1402/08/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effects of different doses of Melatonin on pain control after surgery and their effects on the need for opioid and non-opioid analgesics in patients who are candidates for spinal anesthesia: a double-blind clinical trial

Public title

Evaluation the effects of different doses of Melatonin on pain control after surgery and their effects on the need for opioid and non-opioid analgesics in patients who are candidates for spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Be over 18 years old Candidate patients for spinal anesthesia Completing the informed consent form

Exclusion criteria:

Patients with liver failure (liver enzymes more than triple the normal limit) Patients with renal failure (GFR<60) pregnancy Patients with brain tumors. Patients who have a history of neurological and psychological diseases People who take warfarin Drug abuse History of sensitivity to melatonin The patient's unwillingness to participate in the study

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **152**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization process is done with Random Allocation Software and the block method is used, and the block size is 8 people and the number of blocks is 19 items. The randomization unit is individual. In order to hide the treatment allocation, the list of treatments are placed in sealed and numbered envelopes (to preserve the order of the sequence).

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization will be done based on the method of random block permutations of eight. Before starting the sampling, the drugs are coded at the time of manufacture in the Faculty of Pharmacy. And the drugs are given to volunteer patients by a nurse who has no role in data collection and data analysis. The participant and the researcher who collects the data and evaluates the patients do not know the type of patient intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Jundishapur University of Medical Sciences, Ahvaz

Street address

No.83, West Sepid Ave.,Kian abd.,Ahvaz City

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Province

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Postal code

6155739886

Approval date

2023-05-06, 1402/02/16

Ethics committee reference number

IR.AJUMS.REC.1402.087

Health conditions studied

1

Description of health condition studied

postoperative pain

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

Primary outcomes

1

Description

intensity of pain

Timepoint

1, 2, 6, 12 and 24 hours after surgery

Method of measurement

Visual Analogue Scale

2

Description
Dosage of opioid analgesic after surgery
Timepoint
1, 2, 6, 12 and 24 hours after surgery
Method of measurement
Calculate the amount of medicine used

3

Description
The dosage of non-opioid analgesic after surgery
Timepoint
1, 2, 6, 12 and 24 hours after surgery
Method of measurement
Calculate the amount of medicine used

Secondary outcomes

1

Description
Side effects include drowsiness, fatigue, confusion, headache, irritability, nausea, vomiting and itching
Timepoint
1, 2, 6, 12 and 24 hours after surgery
Method of measurement
Ask the patient

Intervention groups

1

Description
Intervention group: Group A received Melatonin sublingual tablet 3 mg (Norm Life manufactured by Amin Pharmaceutical Company, Iran)+ 1 sublingual placebo tablet (made in the growth center of Ahvaz Faculty of Pharmacy)
Category
Treatment - Drugs

2

Description
Intervention group: Group B received Melatonin sublingual tablet 10 mg (Norm Life manufactured by Amin Pharmaceutical Company, Iran) + 1 sublingual placebo tablet (made in the growth center of Ahvaz Faculty of Pharmacy)
Category
Treatment - Drugs

3

Description
Intervention group: Group C received 2 sublingual tablets of melatonin 10 mg (20 mg in total) (Norm Life manufactured by Amin Pharmaceutical Company, Iran)
Category
Treatment - Drugs

4

Description
Control group: Group D received 2 placebo sublingual tablets (manufactured in the growth center of Ahvaz Faculty of Pharmacy)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Apadana hospital, Ahvaz
Full name of responsible person
Mandana Izadpanah
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Vice-Chancellor of Jundishapur University of Medical Sciences, Ahvaz
Full name of responsible person
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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
Research Vice-Chancellor of Jundishapur University of

Medical Sciences, Ahvaz

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
Iman Abdolkhani

Position
Pharmacy Student

Latest degree
Bachelor

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

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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