Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Effect of preoperative oral Melatonin on pain intensity after cesarean section

Protocol summary

Study aim
Effect of preoperative oral Melatonin on pain intensity after Cesarean section

Design
This study is a double-blind randomized, controlled clinical trial (Phase 3). 204 patients are assigned to three groups by blocking method. The randomization process will be done with Random Allocation Software.

Settings and conduct
The aim of this study was to determine the effect of preoperative Melatonin on postoperative pain intensity in patients undergoing elective cesarean section referred to Imam Khomeini hospital in Sari. Patients are divided into three groups: group A will receive a 5 mg Melatonin tablet, group B will receive a 10 mg Melatonin tablet, and group C will receive a placebo one hour before surgery. Patients and researchers are unaware of group placement. In the operating room, all patients have the same spinal anesthesia under the same anesthesia protocol. Pain intensity, nausea, vomiting, itching and headache in the study groups are evaluated and recorded 2, 6, 12 and 24 hours after surgery. In addition, the patient's first request for postoperative analgesia, the patient's opioid intake within 24 hours of surgery, and the time of the first bed rest are assessed and recorded by the anesthesiologist. It is noteworthy that the placebo required for the study was made of starch and the same color and shape of Melatonin in Sari School of Pharmacy.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients who completed the informed consent form, Lack of sensitivity to Melatonin. Exclusion criteria: Prolongation cesarean section (more than 1.5 hours), third cesarean section (CS III) and higher.

Intervention groups
Group A: One 5 mg melatonin tablet (made by Nature Made, USA) Group B: One 10 mg melatonin tablet (made by Nature Made, USA) Group C: Placebo one hour before surgery

Main outcome variables
Pain intensity and amount of drugs using

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20170220032676N3**
Registration date: **2020-11-18, 1399/08/28**
Registration timing: **prospective**

Last update: **2020-11-18, 1399/08/28**
Update count: **0**
Registration date
2020-11-18, 1399/08/28

Registrant information
Name
Farshad Hassanzadeh Kiabi
Name of organization / entity
Mazandaran University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-12-04, 1399/09/14
Expected recruitment end date
2021-12-05, 1400/09/14
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of preoperative oral Melatonin on pain intensity after cesarean section

Public title

Effect of preoperative oral elatonin on pain intensity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who completed the informed consent form Candidate for non-emergency cesarean section Lack of sensitivity to Melatonin Second cesarean section No history of seizures, diabetes, preeclampsia, eclampsia, hypertension and organ transplantation who do not use drugs to 24 hours before the intervention No alcohol or drug abuse Term pregnancy age

Exclusion criteria:

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **240**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization process is done with Random Allocation Soft ware.The block size is six and the number of blocks is 34. The randomization is done using block method. Unit of randomization is individual. Randomization is done using a table of random numbers and to generate random sequences as online, computer is used. For concealing treatment allocation, the list of treatments are placed in the enclosed and numbered (to maintain order of sequences) envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and researchers will be unaware of group placement, and drugs will be coded at the School of Pharmacy at the time of manufacture.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Mazandaran University of Medical Sciences

Street address

Valiasr bolvard, Sari

City

Sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Approval date

2018-12-18, 1397/09/27

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1397.061

Health conditions studied

1

Description of health condition studied

Cesarean

ICD-10 code

P03.4

ICD-10 code description

Newborn (suspected to be) affected by Cesarean delivery

Primary outcomes

1

Description

Pain intensity

Timepoint

2, 6, 12 and 24 hours after surgery

Method of measurement

Visual analogue scale (VAS)

2

Description

The amount of drugs using

Timepoint

2, 6, 12 and 24 hours after surgery

Method of measurement

Visual analogue scale (VAS)

Secondary outcomes

1

Description

Nausea and vomiting

Timepoint

2, 6, 12 and 24 hours after surgery

Method of measurement

Visual analogue scale (VAS)

2

Description
Itching
Timepoint
2, 6, 12 and 24 hours after surgery
Method of measurement
Visual analogue scale (VAS)

3

Description
Headache
Timepoint
2, 6, 12 and 24 hours after surgery
Method of measurement
Visual analogue scale (VAS)

Intervention groups

1

Description
Intervention group: Group A received 5 mg Melatonin tablets (Made by Nature Made, USA)
Category
Treatment - Drugs

2

Description
Intervention group: Group B received 10 mg Melatonin tablets (Made by Nature Made, USA)
Category
Treatment - Drugs

3

Description
Control group: Melatonin orally, 1 hour before surgery
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Negar Shazdeh Ahmadi
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
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
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Negar Shazdeh Ahmadi
Position
Resident of Anesthesia
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Person responsible for scientific inquiries

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Assistant Professor
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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