

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

Country

Iran (Islamic Republic of)

Phone

+98 11 3304 4000

Email address

fhasanzadehk@mazums.ac.ir

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

Imam Khomeini Hospital, Razi street, Sari

City

Sari

Province

Mazandaran

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4815733971

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+98 11 3304 4000

Email

asanzadehk@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Majid Saeedi

Street address

Valiasr bolvard, Sari

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Sari

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fhasanzadehk@mazums.ac.ir

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

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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asanzadehk@mazums.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Farshad Hasanzadeh Kiabi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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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