# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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
**Postal code**
4815733971
**Phone**
+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
**City**
Sari
**Province**
Mazandaran
**Postal code**
4815733971
**Phone**
+98 11 3304 4000
**Email**
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
**Street address**
Imam Khomeini Hospital, Razi street, Sari
**City**
Sari

**Province**
Mazandaran
**Postal code**
**Phone**
+98 11 3304 4000
**Email**
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
**Street address**
Valiasr bolvard, Sari
**City**
Sari
**Province**
Mazandaran
**Postal code**
4815733971
**Phone**
+98 11 3304 4000
**Email**
fhasanzadehk@mazums.ac.ir

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Mazandaran University of Medical Sciences
**Full name of responsible person**
Dr Negar Shazdeh Ahmadi
**Position**
Resident of Anesthesia
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Anesthesiology
**Street address**
Valiasr bolvard, Sari
**City**
Sari
**Province**
Mazandaran
**Postal code**
4815733971
**Phone**
+98 11 3304 4000
**Email**
asanzadehk@mazums.ac.ir

## 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