Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of different doses of melatonin effect on post operation pain score in patients who underwent cesarean section with spinal anesthesia

Protocol summary

Study aim
Evaluation of different doses of melatonin effect on post operation pain score in patients who underwent cesarean section with spinal anesthesia

Design
This assessment is a clinical trial in phase 3, pregnant women who have indications of selective cesarean delivery and approved by the gynecologist are considered as study group. In this study, 150 cases with inclusion criteria are selected. Patients are classified into three groups by random assignment and by block method, 50 cases in the first intervention group, 50 in the second intervention group and 50 cases in the control group. Accordingly, 24 hours after surgery, the amount of analgesic and mean of pain in patients is evaluated.

Settings and conduct
This study was carried out as a clinical trial at the Ali ibn Abi Talib Hospital, also the study will also be single blinded in which patients will be blinded in study.

Participants/Inclusion and exclusion criteria
Pregnant women who are candidates for cesarean delivery at the age of 18 to 40 years are considered as study group, as well as patients with concomitant liver or kidney disease, chronic cardiovascular disease, history of chronic headache and history of melatonin allergy exclude from the study.

Intervention groups
In the first group, oral melatonin 1.5 mg is used 2 hours before spinal anesthesia. In second group, oral melatonin 3 mg is used 2 hours before spinal anesthesia. Also in third group, placebo is used 2 hours before spinal anesthesia.

Main outcome variables
Severity of pain after cesarean section

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190627044040N1**
Registration date: **2019-08-25, 1398/06/03**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-25, 1398/06/03**
Update count: **0**

Registration date
2019-08-25, 1398/06/03

Registrant information

Name
Setare Haghi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 54 3329 5571

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setarehaghi1368@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-12, 1398/05/21

Expected recruitment end date
2020-01-11, 1398/10/21

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of different doses of melatonin effect on post operation pain score in patients who underwent cesarean section with spinal anesthesia

Public title
The effect of melatonin on pain after cesarean section
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
pregnant women Candidate for delivery of cesarean section Age 18 to 40 years old
Exclusion criteria:
Concurrent liver or kidney disease Chronic cardiovascular disease History of chronic headache Allergy to melatonin
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomization we will use the block method, Accordingly, the patients under study are divided into three groups. The allocation of patients in two groups was based on demographic characteristics and their matching. Based on this, after considering the patients' demographic data, patients were divided into two equal groups of patients, they enrolled in the study and performed desired intervention on them.
Blinding (investigator's opinion)
Single blinded
Blinding description
This means that patients in groups do not know the used drugs, and drugs has similar packaging.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zahedan University of Medical Sciences
Street address
9816743463, Zahedan University of Medical Sciences, Dr. Hesabi Square, Persian Gulf Blvd, Zahedan, Sistan and Baluchestan
City
Zahedan
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Postal code
9816743463
Approval date
2019-05-07, 1398/02/17
Ethics committee reference number
IR.ZAUMS.REC.1398.057

Health conditions studied

1

Description of health condition studied
Pain after elective cesarean section
ICD-10 code
R10.2
ICD-10 code description
Pelvic and perineal pain

Primary outcomes

1

Description
Time of first narcotic application
Timepoint
In the first 24 hours after surgery
Method of measurement
Based on the registration in the checklist

2

Description
The analgesic dose in 24 hours
Timepoint
In the first 24 hours after surgery
Method of measurement
Based on the registration in the checklist

3

Description
Severity of pain
Timepoint
at the end of 24 hours after surgery
Method of measurement
Bsed on VAS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the first group, oral melatonin 1.5 mg is used 2 hours before spinal anesthesia.
Category

Treatment - Drugs

2

Description
Intervention group: In second group, oral melatonin 3 mg is used 2 hours before spinal anesthesia.
Category
Treatment - Drugs

3

Description
Control group: In third group, placebo is used 2 hours before spinal anesthesia.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali ibn Abi Talib Hospital
Full name of responsible person
Setare Haqi
Street address
9816743463, Ali Ibn Abi Talib Hospital, Dr. Hesabi Square, Persian Gulf Blvd, Zahedan, Sistan and Baluchestan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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m_Shahrakim@zaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Shahram Borjian Boroujeni
Position
Anesthesiologist
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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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