

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 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)

Phone

+98 54 3329 5571

Email address

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

Province

Sistan-va-Balouchestan

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

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3329 5564

Email

Setarehaghi1368@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Mohammad Reza Shahraki

Street address

9816743463, Zahedan University of Medical Sciences, Dr. Hesabi Square, Persian Gulf Blvd, Zahedan, Sistan and Baluchestan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3329 5725

Email

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

Street address

9816743463, Zahedan University of Medical Sciences, Dr. Hesabi Square, Persian Gulf Blvd, Zahedan, Sistan and Baluchestan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3329 5564

Email

Setarehaghi1368@gmail.com

Person responsible for scientific 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

Street address

9816743463, Zahedan University of Medical Sciences,
Dr. Hesabi Square, Persian Gulf Blvd, Zahedan, Sistan
and Baluchestan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3329 5564

Email

Setarehaghi1368@gmail.com

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3329 5564

Email

Setarehaghi1368@gmail.com

Person responsible for updating data**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

Street address

9816743463, Zahedan University of Medical Sciences,
Dr. Hesabi Square, Persian Gulf Blvd, Zahedan, Sistan
and Baluchestan

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