

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of two oral precursors of melatonin and gabapentin in female candidates for cesarean section under spinal anesthesia

Protocol summary

Registration timing: **prospective**

Study aim

Comparison of pain and anxiety levels in the placebo group, the melatonin receptor group and the gabapentin receptor group

Last update: **2019-07-21, 1398/04/30**

Update count: **0**

Registration date

2019-07-21, 1398/04/30

Design

Clinical trials with control group, with parallel, double-blind, and randomized groups

Registrant information

Name

samira davodabadi farahani

Name of organization / entity

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Iran (Islamic Republic of)

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Settings and conduct

The patients were randomly allocated to three groups as follows : one group received melatonin , one group received gabapentin and one group received placebo, and the degree of postoperative pain and restlessness measured in Ayatollah Taleghani hospital in Arak.

Participants/Inclusion and exclusion criteria

full-term pregnant women aged 18 to 40 years old undergoing elective cesarean section under spinal anesthesia contraindications for gabapentin or melatonin failed or partial spinal anesthesia gravidity more than 3 Intrauterine Growth Restriction fetal distress history of alcoholism, drug abuse ,convulsion, migraine, dicopathy ,hepatitis ,renal failure ,cardiovascular or pulmonary diseases ,preeclampsia or eclampsia, hypertension, diabete

Recruitment status

Recruitment complete

Funding source

Intervention groups

30 minutes before spinal anesthesia in a group 300 mg of gabapentin and in another group, 3 ml of melatonin is given orally and given to a group placebo. All patients are given 5 ml / kg of serum ringer before spinal anesthesia.

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Pain and anxiety score,the amount of the drug

Trial completion date

empty

General information

Scientific title

Comparison of two oral precursors of melatonin and gabapentin in female candidates for cesarean section under spinal anesthesia

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190120042432N1**

Registration date: **2019-07-21, 1398/04/30**

Public title

Comparison of two oral precursors of melatonin and gabapentin in female candidates for cesarean section

under spinal anesthesia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
full-term pregnant women aged 18 to 40 years old
undergoing elective cesarean section under spinal anesthesia
Exclusion criteria:
contraindications for gabapentin or melatonin failed or partial spinal anesthesia gravidity more than 3
Intrauterine Growth Restriction fetal distress history of alcoholism, drug abuse ,convulsion, migraine, dicopathy ,hepatitis ,renal failure ,cardiovascular or pulmonary diseases ,preeclampsia or eclampsia, hypertension, diabete

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **93**

Randomization (investigator's opinion)
Randomized

Randomization description
بفتقلPatients were randomized according to the charts which was derived from www.randomization.com site.

Blinding (investigator's opinion)
Double blinded

Blinding description
pregnant woman undergoing cesarean section and investigators were blinded to the study treatments.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Arak University of medical sciences, Pardis

site,Sardasht

City
Arak

Province
Markazi

Postal code
3951616558

Approval date
2018-01-24, 1396/11/04

Ethics committee reference number
IR.ARAKMU.REC.1396.297

Health conditions studied

1

Description of health condition studied

Evaluation of pain and anxiety in female candidates for cesarean section under spinal anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The rate of anxiety and postoperative pain

Timepoint

Based on the Verbal Anxiety Scale, anxiety and pain levels is measure before premedication, before spinal anesthesia, five minutes after spinal anesthesia, after exiting the infant, and 15 minutes after spinal anesthesia as well as after surgery and patient transmission to recovery.

Method of measurement

With using the Verbal Anxiety Scale

Secondary outcomes

1

Description

The amount of the analgesic drug

Timepoint

Within 12 hours after surgery

Method of measurement

5 cc syringe using for drug injection

Intervention groups

1

Description

31persons receive 300 mg oral gabapentin, 30 minutes before the onset of spinal anesthesia.

Category

Treatment - Drugs

2

Description

31persons receive 3 mg oral melatonin, 30 minutes before the onset of spinal anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital of Ayatollah Taleghani, Arak

Full name of responsible person

Yazdi Bijan

Street address

Ayatollah Taleghani Hospital, Imam Khomeini Blvd.,Valiasr Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak 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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Yazdi Bijan

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Yazdi Bijan

Position

Assosiate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Associate Professor

Latest degree

Specialist

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All agreed items for publication, such as shared data, study protocol, statistical analysis map, informed consent form, clinical study report, codes used in the database, and data classification system after unidentifiable individuals and maintaining of privacy are publishable.

When the data will become available and for how long

The beginning of the access period one year after the publication of the results

To whom data/document is available

Only scholars working in academia

Under which criteria data/document could be used

In order to use in other studies and scientific work and obtain information for the preparation of the article

From where data/document is obtainable

Daudabadi Farahani Samira To email address
setaresetare004@gmail.com

What processes are involved for a request to access data/document

No need for a specific process and sent by email.

Comments