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

Study aim
Comparison of pain and anxiety levels in the placebo group, the melatonin receptor group and the gabapentin reciptor group
Design
Clinical trials with control group, with parallel, double-blind, and randomized groups
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
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.
Main outcome variables
Pain and anxiety score,the amount of the drug

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190120042432N1**
Registration date: **2019-07-21, 1398/04/30**
Registration timing: **prospective**

Last update: **2019-07-21, 1398/04/30**
Update count: **0**
Registration date
2019-07-21, 1398/04/30

Registrant information
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Recruitment status
Recruitment complete
Funding source

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
Trial completion date
empty

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

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

یفتفلPatients 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

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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
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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
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Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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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 scientifics 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