Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

Assessment of Pregabalin Effects on Post-Dural Puncture Headache After Spinal Anesthesia in Elective Cesarean Surgery.

Protocol summary

Study aim
Determining the pregabalin effects on post-dural puncture headache after spinal anesthesia in elective cesarean surgery.

Design
The double-blind, randomized clinical trial with parallel designs The study was performed on 68 patients in two groups. The randomization method is permuted block randomization.

Settings and conduct
This study was performed in Urmia Shahid Motahari Hospital to assess the effect of pregabalin on reducing the incidence and severity of headache after Dora puncture as a double-blind clinical trial. It should be noted that the patients and their parents were unaware of being in the intervention groups and the clinical evaluator was unaware of the placement of patients in the study groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Pregnant women candidate for elective cesarean surgery with ASA1 and ASA2, obtaining informed consent. Exclusion criteria: Having a history of migraine - the patient with ASA 3 and above, the patients with indications for emergency cesarean section, previous history of post-dural puncture headache, prohibitions of spinal anesthesia for patients who are unable to cooperate will also be excluded from the study.

Intervention groups
The pregnant women who were candidates for elective cesarean section were prescribed 150 mg pregabalin capsule 90 minutes before preparation for surgery.Control group receive placebo.

Main outcome variables
Post-dural puncture headache

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170516033992N4**
Registration date: **2020-12-26, 1399/10/06**
Registration timing: **retrospective**

Last update: **2020-12-26, 1399/10/06**
Update count: **0**

Registration date
2020-12-26, 1399/10/06

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 44 3222 2010
Email address
karami.t@umsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-16, 1398/09/25

Expected recruitment end date
2020-05-14, 1399/02/25

Actual recruitment start date
2019-12-16, 1398/09/25

Actual recruitment end date
2020-05-14, 1399/02/25

Trial completion date
2020-07-20, 1399/04/30

Scientific title
Assessment of Pregabalin Effects on Post-Dural Puncture Headache After Spinal Anesthesia in Elective Cesarean Surgery.

Public title

The effect of pregabalin on post dural puncture headache.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women who undergo elective cesarean section American Society of Anesthesiologists (ASA) 1 and 2

Exclusion criteria:

Having a history of migraine The patient with ASA 3 and above The patients with indications for emergency cesarean section Previous history of post-dural puncture headache Prohibitions of spinal anesthesia for patients who are unable to cooperate

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **136**

Actual sample size reached: **136**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be conducted based on the permuted block randomization method. We will have 34 blocks of 4 letters in which every block contains 2 A and 2 B e.g. ABAB. Each block will have four capacities. Then, in each block, subjects will be randomly assigned to intervention (n=68) or placebo (n=68) groups. Random assignment will be done using a random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients in the study are behind the investigator and the statistical analyzer is unaware of how the groups are allocated.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

No. 30, Jahad Sq., Resalat St., Urmia University of Medical Sciences, Urmia, Iran

City

Urmia

Province

West Azarbaijan

Postal code

5715833631

Approval date

2019-12-14, 1398/09/23

Ethics committee reference number

IR.UMSU.REC. 1398.341

Health conditions studied

1

Description of health condition studied

Headach

ICD-10 code

R51

ICD-10 code description

Headache

Primary outcomes

1

Description

Severity of headach

Timepoint

Evaluation of the incidence and Severity of post-dural puncture headache in the interval of 6,12, 24, 48, 72 hours after spinal anesthesia

Method of measurement

Visual analog scale

Secondary outcomes

1

Description

post-dural puncture headache

Timepoint

6,12, 24, 48, 72 hours after spinal anesthesia

Method of measurement

Visual analog scale

2

Description

Timepoint

Method of measurement

Intervention groups

1

Description

Intervention group: pregnant women, candidates for

elective cesarean section were prescribed 150 mg pregabalin capsule made by Pfizer 90 minutes before preparation for surgery.

Category

Treatment - Drugs

2

Description

Control group: pregnant women, candidates for elective cesarean section were prescribed placebo capsule 90 minutes before preparation for surgery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Shahid Motahari University Hospital

Full name of responsible person

Tohid Karami

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No. 30, Jahad Sq., Resalat St., Urmia University of Medical Sciences, Urmia, Iran

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karami.tohid@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

Street address

No. 30, Jahad Sq., Resalat St., Urmia University of Medical Sciences, Urmia, Iran

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Tohid Karami

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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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
Individual data will be confidential and the results of the study will be published as an article.

When the data will become available and for how long
2020

To whom data/document is available
The article will be published internationally.

Under which criteria data/document could be used
There is no special condition.

From where data/document is obtainable
Internet

What processes are involved for a request to access data/document
Searching on the databases

Comments