Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Survey effect of Transnasal Sphenopalatin ganglion nerve block for treatment of postdural puncture headache after spinal anesthesia in cesarean section.

Protocol summary

Study aim
the effect of sphenopalatine ganglion block in treating PDPH following spinal anesthesia in cesarean section.

Design
The clinical trial has a control group, with parallel groups without blinding, randomized phase 3 through the random function of Excel software on 60 patients.

Settings and conduct
Pregnant women undergoing cesarean section with spinal anesthesia, who present with headache while standing after dura mater puncture at Nik Nafs and Ali Ibn Abi Talib (AS) maternity hospital in Rafsanjan, are performed using a numerical rating scale. Their headache is graded in terms of severity. In this way, based on the intensity of the pain, the patient is asked to give a score to the headache they are currently suffering from and this score is recorded. The first group (intervention), is the group receiving sphenopalatine ganglion block through The nose and the second group is the control group receiving drug treatment (pain reliever and serum).

Participants/Inclusion and exclusion criteria
Inclusion criteria: pregnant women undergoing cesarean section with spinal anesthesia who present with a headache after dural puncture. Exclusion criteria include depression disorders, other mental disorders, history of drug or alcohol addiction, previous neurological headaches including migraine, nervous headache, etc., and previous brain defects and pre-eclampsia.

Intervention groups
the group receiving sphenopalatine ganglion block through the nose and the other group receiving pain analgesia and serum

Main outcome variables
Postural puncture headache

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190817044544N4**
Registration date: **2022-11-05, 1401/08/14**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-05, 1401/08/14**
Update count: **0**

Registration date
2022-11-05, 1401/08/14

Registrant information

Name
Fatemeh Jadidi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 34 3428 0185

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-15, 1401/02/25

Expected recruitment end date
2022-11-16, 1401/08/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Survey effect of Transnasal Sphenopalatin ganglion nerve block for treatment of postdural puncture headache after spinal anesthesia in cesarean section.

Public title
Survey of PDPH through sphenopalatine ganglion block

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women undergoing cesarean section are performed with spinal anesthesia who come with PDPH. At the beginning, headache characteristics (inclusion criteria) are examined, which include frontooccipital headache and positional headache.

Exclusion criteria:
It includes depression disorders, other mental disorders, history of drug or alcohol addiction, previous neurological headaches including migraines, neuralgia headaches, etc., and previous brain defects and pre-eclampsia.

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization: First, by referring the samples to the pain clinic of Rafsanjan University of Medical Sciences, 60 cases are selected based on the entry and exit criteria, and then they are divided into two groups, intervention, and control groups. In this method, by merging the cards together (cards shuffling), one card is removed and its assignment to the intervention or control group is recorded, and that card is removed from the other cards. Then the cards are merged again and another card is drawn. This process continues until reaching a random sequence corresponding to the sample size of 30 cases for the intervention group and 30 cases for the control group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of rafsanjan University of Medical Sciences

Street address
Rafsanjan, Imam Ali Boulevard

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rafsanjan

Province
Kerman

Postal code
7717933777

Approval date
2022-05-14, 1401/02/24

Ethics committee reference number
IR.RUMS.REC.1401.031

Health conditions studied

1

Description of health condition studied
Postural puncture headache

ICD-10 code
O74.5

ICD-10 code description
Spinal and epidural anaesthesia-induced headache during labour and delivery

Primary outcomes

1

Description
postural puncture headache

Timepoint
Before the intervention, one, six, 24 hours after the intervention

Method of measurement
Numerical rating scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group :Group receiving sphenoplatin ganglion block through the nose , In the patient lying down, two cc of 2% lidocaine are inserted into the middle turbinate of the nose using an applicator and the drug is discharged next to the sphenopalatine ganglion, then the patient remains in the same lying position for five minutes.

Category

Treatment - Drugs

2

Description
Control group: They receive drug treatment (analgesic and serum).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rafsanjan University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rafsanjan 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
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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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

Researchers working in scientific centers

Under which criteria data/document could be used

Use of data for review studies

From where data/document is obtainable

Rafsanjan University of Medical Sciences

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

Rafsanjan University of Medical Sciences, Research Assistant

Comments