

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 34 3428 0185

Email address

dr.fjadidi@rums.ac.ir

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

City

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

Saeid Khoram nia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Rafsanjan University of Medical Sciences

Full name of responsible person

Saeid Khoram Nia

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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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