

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of the Effect of Sphenopalatine Ganglion Block in the Treatment of Post-Dural Puncture Headache (PDPH) in Patients Undergoing Spinal Anesthesia at Allameh Bohlool Gonabadi Hospital

Protocol summary

Study aim

The effect of sphenopalatine nerve block in the treatment of post-spinal anesthesia headache in patients undergoing spinal anesthesia.

Design

Clinical trial with two control and intervention groups with parallel groups, triple-blind, randomized with sealed envelope, phase 3 on 20 patients

Settings and conduct

Sphenopalatine nerve block is performed transnasally using a cotton swab soaked in 2% lidocaine. The patient is placed in a supine position with the neck slightly bent backward with a pillow or towel. Then, a swab is inserted into the nostril parallel to the floor of the nose until it reaches the posterior nasopharynx, above the middle turbinate. The swab is kept in each nostril for five to ten minutes and then removed. All of these procedures were also performed in group B, except that in this group, the swab is soaked in distilled water instead of lidocaine.

Participants/Inclusion and exclusion criteria

Adult patients aged 18 to 65 years Occurrence of post-dural puncture headache Headache intensity of at least 4 out of 10 based on VAS Patients with stable hemodynamic status at the time of treatment No history of allergy or hypersensitivity to lidocaine No coagulation disorders No active infection or inflammation in the facial or nasal are No peripheral or central nervous system diseases No severe cardiovascular diseases or chronic renal and hepatic failure No receipt of alternative treatments for post-dural puncture headache No mental or psychological disabilities No history of surgery or trauma in the head and face region

Intervention groups

In the intervention group, sphenopalatine block was performed through the nose using a swab soaked in 2% lidocaine In the control group, sphenopalatine block was performed through the nose using a swab soaked in

distilled water

Main outcome variables

Headache reduction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200501047254N4**

Registration date: **2026-02-04, 1404/11/15**

Registration timing: **registered_while_recruiting**

Last update: **2026-02-04, 1404/11/15**

Update count: **0**

Registration date

2026-02-04, 1404/11/15

Registrant information

Name

Fatemeh Pouladkhay

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 3360

Email address

pouladkhay.fatemeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-23, 1404/07/01

Expected recruitment end date

2026-04-21, 1405/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Sphenopalatine Ganglion Block in the Treatment of Post-Dural Puncture Headache (PDPH) in Patients Undergoing Spinal Anesthesia at Allameh Bohlool Gonabadi Hospital

Public title

The effect of sphenopalatine anesthesia in controlling headache after spinal anesthesia.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Headache after spinal anesthesia Headache severity of at least 4 out of 10 on a visual analog pain scale(VAS) Patients with stable hemodynamic status at the time of treatment Informed consent No history of allergy or hypersensitivity to lidocaine No active infection or inflammation in the facial or nasal area (site of sphenopalatine block) No peripheral or central nervous system diseases that could interfere with outcome assessment No severe cardiovascular diseases or chronic renal and hepatic failure No history of surgery or trauma in the head and face region that would limit the safe performance of the block No prior receipt of alternative treatments for post-dural puncture headache (PDPH), such as epidural blood patch, and no need for supplemental treatments during the study Absence of coagulation disorders No mental or psychological disabilities that impair the ability to cooperate or respond to questionnaires

Exclusion criteria:

Unwillingness to continue participating in the research

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

For simple randomization of participants into control and intervention groups, individuals will be randomly assigned to one of the two groups using sealed envelopes.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The sampling was conducted in a triple-blind manner

such that the swab used for the sphenopalatine block was prepared by a project collaborator, and neither the researcher responsible for sampling nor the patient was aware of the type of medication the swab was impregnated with. Finally, the participants' data in groups A and B were entered into the SPSS software, and the data analyst was blinded to the nature of the groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Gonabad university of medical sciences

Street address

Side of Asian Road - Gonabad University of Medical Sciences Campus

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2025-12-01, 1404/09/10

Ethics committee reference number

IR.GMU.REC.1404.124

Health conditions studied**1****Description of health condition studied**

post-dural puncture headache

ICD-10 code

G97.1

ICD-10 code description

Other reaction to spinal and lumbar puncture

Primary outcomes**1****Description**

VAS Pain score

Timepoint

Headache measurement before intervention and at 15 and 30 minutes and 1, 2, 4, 6, 8, 12, 24 hours after intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Tachycardia

Timepoint

heart rate measurement before intervention and at 15 and 30 minutes and 1, 2, 4, 6, 8, 12, 24 hours after intervention

Method of measurement

checklist

Intervention groups

1

Description

Intervention group: Performing a sphenopalatine nerve block under the supervision of an anesthesiologist, transnasally, using a cotton swab soaked in 2% lidocaine.

Category

Treatment - Drugs

2

Description

Control group: Performing a sphenopalatine nerve block under the supervision of an anesthesiologist, transnasally, using a cotton swab soaked in distilled water.

Category

Placebo

Recruitment centers

empty

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Fatemeh Pouladkhay

Street address

Sadi Street, Sadi 25

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Email

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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

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Fatemeh Pouladkhay

Position

Instructor, member of the operating room group

Latest degree

Master

Other areas of specialty/work

Others

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Person responsible for scientific inquiries

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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

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after de-identifying individuals.

When the data will become available and for how long

one year after publication

To whom data/document is available

Researchers and academic institutions

Under which criteria data/document could be used

Conducting secondary research and analysis on data

From where data/document is obtainable

Fatemeh Pouladkhay

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

Contact via email will be responded to promptly.

Comments