Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 scienses
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
City
Gonabad
Province
Razavi Khorasan
Postal code
9691738135
Phone
+98 51 5722 3360
Email
Pouladkhay.fatemeh@gmail.com
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
Street address
Department of Operating Room, School of Paramedical Sciences, Gonabad University of Medical Sciences, Gonabad, Khorasan Razavi
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Phone
+98 51 5722 3028
Fax
+98 51 5722 3814
Email
pouladkhay.fatemeh@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Fatemeh Pouladkhay
Position
Instructor, faculty member of the operating room group
Latest degree
Master
Other areas of specialty/work
Others
Street address

Department of Operating Room, School of Paramedical Sciences, Gonabad University of Medical Sciences, Gonabad, Khorasan Razavi

City
Gonabad

Province
Razavi Khorasan

Postal code
9691793718

Phone
+98 51 5722 3028

Fax
+98 51 5722 3814

Email
pouladkhay.fatemeh@gmail.com

Person responsible for updating data

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

Street address
Department of Operating Room, School of Paramedical Sciences, Gonabad University of Medical Sciences, Gonabad, Khorasan Razavi

City
Gonabad

Province
Razavi Khorasan

Postal code
9691793718

Phone
+98 51 5722 3028

Fax
+98 51 5722 3814

Email
pouladkhay.fatemeh@gmail.com

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