Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of sphenopalatine ganglion block via transmucosal and transcoronoid approach for trigeminal autonomic cephalgia

Protocol summary

Study aim
This study was designed to compare the outcomes of SPG block administered via transmucosal and transcoronoid approaches in patients with autonomic cephalalgia

Design
prospective quasi-experimental comparative study

Settings and conduct
Department of Pain Medicine, CMH Rawalpindi over a period of six months

Participants/Inclusion and exclusion criteria
Inclusion Criteria Patients aged 18–65 years with a clinical diagnosis of trigeminal autonomic cephalalgia were included. Eligible participants were those with inadequate response to at least six months of standard oral pharmacotherapy (including amitriptyline, duloxetine, venlafaxine, pregabalin or gabapentin) and who reported moderate to severe pain intensity (defined as a Numeric Rating Scale - NRS score greater than 6). Only patients without evidence of secondary headache disorders or underlying dental or palatal pathology were enrolled. Exclusion Criteria Individuals with identifiable dental or palatal abnormalities contributing to facial pain, patients with secondary headache etiologies such as intracranial tumors or hemorrhage, patients with structural abnormalities including cleft lip/ palate or nasal septal defects, history of trauma or surgical intervention, patients with significant coagulopathy, hepatic or renal dysfunction, as well as those with a history of malignancy, were excluded from the study.

Intervention groups
Group A underwent sphenopalatine ganglion (SPG) block via the transmucosal approach, whereas Group B received the block through fluoroscopy guided transcoronoid approach.

Main outcome variables
The primary outcome was the mean change in NRS score from baseline to one month.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260706070085N1**
Registration date: **2026-07-20, 1405/04/29**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-20, 1405/04/29**
Update count: **0**

Registration date
2026-07-20, 1405/04/29

Registrant information

Name
Khurram Liaqat

Name of organization / entity
Combined Military Hospital Rawalpindi

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Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-07-15, 1405/04/24

Expected recruitment end date
2026-10-14, 1405/07/22

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of sphenopalatine ganglion block via transmucosal and transcoronoid approach for trigeminal autonomic cephalgia

Public title
Comparison of sphenopalatine ganglion block via transmucosal and transcoronoid approach for trigeminal autonomic cephalgia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged 18–65 years with a clinical diagnosis of trigeminal autonomic cephalalgia were included. Eligible participants were those with inadequate response to at least six months of standard oral pharmacotherapy (including amitriptyline, duloxetine, venlafaxine, pregabalin or gabapentin) and who reported moderate to severe pain intensity (defined as a Numeric Rating Scale - NRS score greater than 6). Only patients without evidence of secondary headache disorders or underlying dental or palatal pathology were enrolled.

Exclusion criteria:
Individuals with identifiable dental or palatal abnormalities contributing to facial pain Patients with secondary headache etiologies such as intracranial tumors or hemorrhage, patients with structural abnormalities including cleft lip/ palate or nasal septal defects, history of trauma or surgical intervention Patients with significant coagulopathy, hepatic or renal dysfunction, as well as those with a history of malignancy, were excluded from the study.

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

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients were unaware of the type of intervention being done to avoid any bias.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Combined Military Hospital

Street address
Tamiz ud Din Road

City
Rawalpindi

Postal code
000000

Approval date
2026-05-28, 1405/03/07

Ethics committee reference number
634

Health conditions studied

1

Description of health condition studied
Trigeminal autonomic cephalalgias (TACs), including cluster headache and related disorders characterized by unilateral trigeminal pain with ipsilateral autonomic features, represent a relatively uncommon yet highly disabling group of primary headache disorders.

ICD-10 code
G44.0

ICD-10 code description
Cluster headaches and other trigeminal autonomic cephalgias (TAC)

Primary outcomes

1

Description
The primary outcome was the mean change in NRS score from baseline to one month.

Timepoint
Follow-up assessments were conducted at one week and one month after the intervention.

Method of measurement
Pain intensity was recorded using the Numeric Rating Scale at each follow-up visit.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group A underwent sphenopalatine ganglion (SPG) block via the transmucosal approach

Category
Treatment - Other

2

Description
Intervention group: Group B received the block through fluoroscopy guided transcoronoid approach.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Combined Military Hospital
Full name of responsible person
Khurram Liaqat
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Sponsors / Funding sources

1

Sponsor
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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
Combined Military Hospital
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
Combined Military Hospital Rawalpindi
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Khurram Liaqat
Position
Resident Pain Medicine
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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
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
Comparison of sphenopalatine ganglion block via transmucosal and transcoronoid approach for trigeminal autonomic cephalgia
When the data will become available and for how long
6 months after Publication
To whom data/document is available
Journal publishing article
Under which criteria data/document could be used
Journal publishing it
From where data/document is obtainable
Journal publishing it
What processes are involved for a request to access data/document
Can be requested from Journal publishing it
Comments