

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 cephalgia

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 cephalgia 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 Liaquat

Name of organization / entity

Combined Military Hospital Rawalpindi

Country

Pakistan

Phone

+92 300 9834841

Email address

drkhurramliaquat@gmail.com

Recruitment status

recruiting

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 cephalgia 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 cephalgias (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 transcatheter approach.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Combined Military Hospital

Full name of responsible person

Khurram Liaquat

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Combined Military Hospital

Full name of responsible person

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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

Full name of responsible person

Khurram Liaquat

Position

Resident Pain Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Position

Resident Pain Medicine

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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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