Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the Effectiveness of Conventional Radiofrequency Versus Combined Pulsed-Conventional Radiofrequency in the Treatment of Drug-Resistant Trigeminal Neuralgia: A Randomized Clinical Trial

Protocol summary

Study aim

To compare the efficacy of conventional radiofrequency (CRF) and pulsed radiofrequency combined with conventional radiofrequency (PRF+CRF) in reducing pain intensity, improving quality of life, and reducing treatment-related adverse events in patients with drug-resistant classical trigeminal neuralgia.

Design

Randomized, single-blind, parallel-group clinical trial with 1:1 allocation. Block randomization with block size 4 will be used. Total sample size is 28.

Settings and conduct

This randomized clinical trial will be conducted at the Pain Clinic of Imam Khomeini Hospital Complex, Tehran University of Medical Sciences. Eligible participants will be enrolled after providing written informed consent and randomly allocated to the CRF or PCRF group. The study is single-blind, with participants and outcome assessors blinded to treatment allocation. Participants will be followed for 3 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18–80 years, classical trigeminal neuralgia (ICHD-3), ≥50% pain reduction after diagnostic block, ASA I–II, written informed consent, and failure of standard two- or three-drug therapy. Exclusion criteria: Secondary trigeminal neuralgia, coagulopathy or non-discontinuable anticoagulant therapy, active infection, allergy to lidocaine or dexamethasone, previous trigeminal RF or surgery, unstable cardiopulmonary disease, pregnancy, or breastfeeding.

Intervention groups

Group 1: Conventional radiofrequency (CRF). Group 2: Pulsed radiofrequency combined with conventional radiofrequency (PCRF). Participants will be randomly allocated in a 1:1 ratio.

Main outcome variables

Pain intensity measured by the Numeric Rating Scale (NRS); quality of life assessed using the SF-36 questionnaire; treatment-related adverse events.

General information

Reason for update

Acronym

PCRF-TN

IRCT registration information

IRCT registration number: **IRCT20260623069925N1**
Registration date: **2026-06-26, 1405/04/05**
Registration timing: **prospective**

Last update: **2026-06-26, 1405/04/05**
Update count: **0**

Registration date

2026-06-26, 1405/04/05

Registrant information

Name

asma amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-23, 1405/05/01

Expected recruitment end date

2026-10-23, 1405/08/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Conventional Radiofrequency Versus Combined Pulsed-Conventional Radiofrequency in the Treatment of Drug-Resistant Trigeminal Neuralgia: A Randomized Clinical Trial

Public title
Comparison of Two Radiofrequency Techniques for the Treatment of Drug-Resistant Trigeminal Neuralgia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 80 years Diagnosis of classical trigeminal neuralgia according to ICHD-3 criteria Positive response to diagnostic block with at least 50% reduction in pain intensity based on the NRS ASA physical status I or II Ability to understand the study and sign the informed consent form Failure to respond adequately to standard two-drug or three-drug therapy
Exclusion criteria:
Refusal to participate in the study or failure to provide informed consent Secondary trigeminal neuralgia due to multiple sclerosis or tumor lesions Coagulation disorders or use of anticoagulant drugs that cannot be discontinued Active local or systemic infection Known allergy to lidocaine or dexamethasone History of open trigeminal surgery or previous radiofrequency procedures Unstable cardiopulmonary disease Pregnancy or breastfeeding
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **28**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible participants who provide written informed consent will be randomly allocated in a 1:1 ratio to the Conventional Radiofrequency group or the Pulsed Radiofrequency plus Conventional Radiofrequency group using block randomization. The random allocation sequence will be generated using statistical software, and allocation concealment will be ensured by sequentially numbered, opaque, sealed envelopes.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is a single-blind randomized clinical trial. Participants will be blinded to the allocated intervention (Conventional Radiofrequency or Pulsed Radiofrequency combined with Conventional Radiofrequency). Outcome assessors responsible for data collection and clinical outcome assessment will also be blinded to treatment allocation. The physician performing the procedure (investigator) will not be blinded because of the nature of the intervention. Clinical care providers and data analysts will also not be blinded.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Neuroscience Institute, Tehran University of Medical Sciences
Street address
No. 8, Unit 4, Golparvar Alley, Mousavi St., Shahrara Neighborhood, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1445753955
Approval date
2026-06-24, 1405/04/03
Ethics committee reference number
IR.TUMS.NI.REC.1405.035

Health conditions studied

1

Description of health condition studied
Trigeminal Neuralgia
ICD-10 code
G50.0
ICD-10 code description
Trigeminal neuralgia

Primary outcomes

1

Description
Pain intensity measured by the Numerical Rating Scale (NRS)
Timepoint
Pain intensity will be measured at baseline, before the intervention, and then 1 month and 3 months after the

intervention.

Method of measurement

Pain intensity will be measured using the Numerical Rating Scale (NRS), scored from 0 to 10.

Secondary outcomes

1

Description

Quality of life measured by the 36-Item Short Form Health Survey (SF-36)

Timepoint

Before the intervention, 1 month after the intervention, and 3 months after the intervention

Method of measurement

Quality of life will be measured using the 36-Item Short Form Health Survey (SF-36).

2

Description

Incidence of intervention-related adverse events

Timepoint

Before the intervention, 1 month after the intervention, and 3 months after the intervention

Method of measurement

Adverse events will be assessed by clinical examination, patient interview, and documentation of all intervention-related adverse events, including facial numbness, dysesthesia, masticatory muscle weakness, decreased corneal reflex, and other potential complications.

Intervention groups

1

Description

Control group: Participants will undergo conventional radiofrequency (CRF) treatment of the trigeminal nerve. After fluoroscopic needle placement and confirmation by sensory and motor stimulation, conventional radiofrequency will be applied at 70°C for 60 seconds in three consecutive cycles using a four-channel NeuroTherm radiofrequency generator (NeuroTherm, USA).

Category

Treatment - Devices

2

Description

Intervention group:Participants will undergo pulsed radiofrequency (PRF) at a maximum temperature of 42°C for 240 seconds (20-ms pulse width, 2 Hz), followed immediately by conventional radiofrequency (CRF) at 70°C for 60 seconds in two consecutive cycles using a four-channel NeuroTherm radiofrequency generator (NeuroTherm, USA).

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Pain Clinic, Imam Khomeini Hospital, Tehran University of Medical Sciences

Full name of responsible person

Asma Amiri

Street address

Pain Clinic, Imam Khomeini Hospital Complex, End of Keshavarz Blvd, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Street address

No. 21, Dameshgh St., Vali-e Asr Ave., Tehran, Iran

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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

Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Asma Amiri

Position
Fellow of Pain Medicine

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available