

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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), $\geq 50\%$ 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)

Phone

+98 21 8826 8180

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

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Province

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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

Dr. Ramin Kordi

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

+98 21 8490 1000

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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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Position

Fellow of Pain Medicine

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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