

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of Pulsed Radiofrequency and Transcutaneous electrical nerve stimulation on decreasing of Diabetic neuropathy symptoms in Lower extremity in patients who did not respond to medications

Protocol summary

Summary

This study is a randomized-controlled trial. The sample of study is diabetic patients who have been referred to the Pain clinic because of persistent pain and paresthesia in lower extremity. The entire patients are enrolled in the study after consideration of inclusion and exclusion criteria and informed consents are obtained. All the study subjects will be followed-up regarding pain and paresthesia in lower extremity with numeric rating scale score. The study patients are divided into two groups. Group 1 patients receive pulsed radiofrequency on lumbar sympathetic chain and group 2 patients receive TENS on lower extremity. patients will be followed with numeric rating scale score due to their severity of pain and paresthesia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212166186N1**

Registration date: **2012-12-20, 1391/09/30**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-12-20, 1391/09/30

Registrant information

Name

Bahram Naderi Nabi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

research office of anesthesiology and pain management,
guilan university of medical sciences

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-12-21, 1392/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Pulsed Radiofrequency and Transcutaneous electrical nerve stimulation on decreasing of Diabetic neuropathy symptoms in Lower extremity in patients who did not respond to medications

Public title

Comparison of Pulsed Radiofrequency and TENS on decreasing of Diabetic neuropathy symptoms in Lower extremity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: diabetic patients who have been referred to the "Pain clinic" because of persistent pain and paresthesia in lower extremity who did not respond to oral medications. Exclusion criteria: coagulopathy; anti platelet and anticoagulant therapy; local infection at the procedure site; advanced stages of diabetic neuropathy

without paresthesia and pain; addiction; cardiac pacemaker; epilepsy and pregnancy

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

research office of guilan university of medical sciences

Street address

gas square, western shahid beheshti blvd, in front of sepah bank

City

rasht

Postal code

4193893345

Approval date

2012-10-23, 1391/08/02

Ethics committee reference number

1910231201

Health conditions studied**1****Description of health condition studied**

Diabetes mellitus

ICD-10 code

G99*

ICD-10 code description

Diabetic autonomic neuropathy

Primary outcomes**1****Description**

pain

Timepoint

before intervention, 7th day and 1st month and 3rd month after intervention

Method of measurement

numeric rating scale score

2**Description**

paresthesia

Timepoint

before intervention, 7th day and 1st month and 3rd month after intervention

Method of measurement

numeric rating scale score

Secondary outcomes

empty

Intervention groups**1****Description**

for TENS group after cleaning the skin with alcohol, patch electrodes will be attached to the skin of lateral inferior part of knee and forfoot. then electrical impulses will be generated with 80 Hz and 50 mA for 20 minutes. there will be 10 sessions of TENS daily.

Category

Treatment - Devices

2**Description**

for RF group in operation room with fluoroscopic guide, the patient will be in prone position and RF needle will be inserted percutaneously from lumbar region to the lumbar sympathetic chain in anterolateral portion of L2 L3 and L4 vertebrates. the needle position will be approved by injection of omnipaque 240 and sensory and motor stimulating test.patients will receive 3 cycles of pulsed radiofrequency lasting for 180 seconds for each of the vertebrates.

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

poursina hospital

Full name of responsible person

amir hossein fathi
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namjoo street
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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
research office of anesthesiology and pain, guilan university of medical sciences
Full name of responsible person
abas sedighinejad
Street address
namjoo street, poursina hospital
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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
research office of anesthesiology and pain, guilan university of medical sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
guilan university of medical sciences
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty
Analytic Code
empty
Data Dictionary
empty