Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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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
Street address
namjoo street
City
rasht

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
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namjoo street, poursina hospital
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rasht
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
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assistant professor of anesthesiology-fellowship of interventional pain management
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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