Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 2026

A Comparison of the Effectiveness of Transcutaneous Electrical Nerve Stimulation and Duloxetine on Diabetic Peripheral Neuropathic pain

Protocol summary

Study aim
A Comparison of the Effectiveness of Transcutaneous Electrical Nerve Stimulation and Duloxetine on the pain caused by diabetic peripheral neuropathy

Design
A one-blinded,randomized clinical trial,phase 3 with parallel groups,design of 60 patients.

Settings and conduct
This study will be done at Pursina Hospital and Guilan Pain Clinic on patients with diabetic peripheral neuropathic pain who have not responded to previous therapies.60 patients randomly and with quadruple block method will be divided in two groups of TENS and Duloxetine.Patients will be visited weekly,during the first 4 weeks and then every 4 weeks.Patients will be followed up for 3 months. Patients will be assessed based on NRS (Numerical Rating Scale).Finally,results will be compared in two groups.In this study,the physician that evaluates patients after treatment is blind.But because of the method of administration,patients are aware of their treatment.

Participants/Inclusion and exclusion criteria
Entry criteria:patients type I or II diabetes mellitus,with diabetic neuropathic pain Resistant to usual drug treatments. Non-entry criteria:Having a pacemaker or defibrillator,Other neuropathies with causes other than diabetes.

Intervention groups
Tense group:In this group,an electrode will be placed above the wrist and another below the knee.Patients will receive a tense with the stimulator (E 3 model, Omran Location) for 20 minutes with these Specifications(80 Hz, 50 Amp, 0.2 ms Square Pulse 2 to 3 times sensory threshold).For four weeks, sessions will be held Every other day.Then, twice a week for three months. Duloxetine group:In this group,(20 milligrams tablets,Abidi Company),patients will receive 20 milligrams per day in the first week,40 milligrams per day in the second week and 60 milligrams since week 3 to 12.

Main outcome variables
Pain caused by diabetic peripheral neuropathy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110413006186N13**
Registration date: **2019-05-27, 1398/03/06**
Registration timing: **prospective**

Last update: **2019-05-27, 1398/03/06**
Update count: **0**

Registration date
2019-05-27, 1398/03/06

Registrant information

Name
Bahram Naderi Nabi

Name of organization / entity
Guilan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-22, 1398/04/01

Expected recruitment end date
2019-12-22, 1398/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A Comparison of the Effectiveness of Transcutaneous Electrical Nerve Stimulation and Duloxetine on Diabetic Peripheral Neuropathic pain

Public title
The effect of electric stimulation through skin and duloxetine on diabetic neuropathic pain
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
patients type I or II diabetes mellitus, with diabetic neuropathic pain Resistant to usual drug treatments, at least for 6 months Minimum Pain Rating 4 based on Numerical Rating Having normal creatinine and CBC blood counts HBA1C less than 8%.
Exclusion criteria:
Having a pacemaker or defibrillator Having brain stimulators Infection or inflammation at the site of electrodes Other neuropathies with causes other than diabetes Alcohol consumption history Malignant history Tens Records history Pregnancy Bipolar patients Duloxetine contraindications such as liver or kidney failure and MAO-I simultaneous use
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
To produce random sequences in this clinical trial, we will use this site: http://www.graphpad.com/quickcalcs/index.cfm.This study will be conducted as a pilot study in two groups of 30. The responsible physician for this study will randomly divide the patients into TENS (T) and Duloxetine (D) groups based on quadruple block method.
Blinding (investigator's opinion)
Single blinded
Blinding description
Three months before starting the treatment, patients will be asked to discontinue all their analgesics and receive gabapentin 400-300 milligrams daily. After three months, if the symptoms of the patient are adequately controlled and there were no side effects, They will be excluded. Other patients who did not respond to the treatment will be randomly assigned to TENS (T) or Dolextine (D) by the responsible physician. In this study, the physician that evaluates patients after treatment is blind and unaware of the treatment group. But because of the method of administration, patients are aware of their treatment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee Of Guilan University Of Medical Sciences
Street address
Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street
City
Rasht
Province
Guilan
Postal code
4144666949
Approval date
2019-05-11, 1398/02/21
Ethics committee reference number
IR.GUMS.REC.1398.052

Health conditions studied

1

Description of health condition studied
Diabetic Peripheral Neuropathy
ICD-10 code
E11.40
ICD-10 code description
Type 2 diabetes mellitus with diabetic neuropathy, unspecified

Primary outcomes

1

Description
Pain caused by diabetic peripheral neuropathy
Timepoint
Before starting treatment, 1 month and 3 months after starting treatment
Method of measurement
Patients will be assessed based on NRS (Numerical Rating Scale)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Three months before the start of treatment, patients will be asked to discontinue all their analgesics and receive gabapentin 400-300 milligrams per day. If the symptoms of the patient were not adequately controlled with this drug and Or have side effects they will be excluded. Three months later, patients will randomly be divided into two groups: TENS (T) and Duloxetine (D).In group T, an electrode above the wrist and another will be placed below the knee. Patients will receive a tense scan (E 3 model, Omran Location) for 20 minutes with a ((80 Hz, 50 Amp, 0.2 ms Square Pulse 2 to 3 times sensory threshold) profile. For four weeks, sessions will be held Every other day. Then, twice a week for three months, patients undergo treatment with Tense. In the first 4 weeks, patients will be visited weekly and then every 4 weeks. Patients will be followed up for 3 months.

Category

Treatment - Devices

2

Description

Intervention group: In the duloxetine group (20 milligrams tablets, the Abidi Pharmaceutical Company), in the first week, 20 milligrams per day, in the second week, 40 milligrams per day , and from week 3 to 12 ,60 milligrams of duloxetine per day will be received. During the first 4 weeks,they will be visited weekly and then every 4 weeks.Patients will be follow up for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Poursina Hospital
Full name of responsible person
Bahram Naderi Nabi
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2

Recruitment center

Name of recruitment center
Guilan pain clinic
Full name of responsible person
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Second Floor,Guilan Building,next to Marlik MRI building,Golbagh Namaz,Rasht
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences
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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
Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Dr Bahram Naderi Nabi

Position

Assosiate professor /Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Position

Research Expert/(MSc) English

Latest degree

Master

Other areas of specialty/work

Research Expert

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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