

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of efficacy of nortriptyline with Transcutaneous Electrical Nerve Stimulation (TENS) on painful peripheral neuropathy in patients with diabetes

Protocol summary

Study aim

The comparison of efficacy of TENS and Nortriptyline on pain reduction in patients with painful peripheral neuropathy caused by diabetes.

Design

This is a controlled double-blind clinical trial study conducted on 42 patients with painful peripheral neuropathy caused by type 1 or type 2 diabetes mellitus. Patients (N = 21 per group) were randomly treated with TENS (18 sessions, each session 30 minutes) or Nortriptyline (25 to 75 mg, once daily) for 6 weeks.

Settings and conduct

This controlled double-blind clinical trial study was conducted on 42 patients with painful peripheral neuropathy caused by type 1 or type 2 diabetes mellitus referring to Golestan Hospital in Ahvaz in 2017-18. Patients were evaluated for side effects and pain relief using visual analog scale (VAS) every week.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years, Consent to participate in the study, Patients with diabetic painful peripheral neuropathy; Exclusion criteria: Patients with other causes of neuropathy, renal dysfunction, liver disease, uncontrolled hypertension, malignancy.

Intervention groups

Treatment with TENS (18 sessions) or Nortriptyline (25 to 75 mg)

Main outcome variables

Pain severity (using VAS) and side effects of the drug

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180212038705N2**

Registration date: **2018-06-26, 1397/04/05**

Registration timing: **retrospective**

Last update: **2018-06-26, 1397/04/05**

Update count: **0**

Registration date

2018-06-26, 1397/04/05

Registrant information

Name

Fariba Heidari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3338 2242

Email address

heidari.p@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-06, 1396/08/15

Expected recruitment end date

2018-03-11, 1396/12/20

Actual recruitment start date

2017-11-06, 1396/08/15

Actual recruitment end date

2018-03-19, 1396/12/28

Trial completion date

empty

Scientific title

Comparison of efficacy of nortriptyline with Transcutaneous Electrical Nerve Stimulation (TENS) on painful peripheral neuropathy in patients with diabetes

Public title

Comparison of efficacy of Nortriptyline with TENS on

painful diabetic peripheral neuropathy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age more than 18 years Type 1 and 2 diabetes Definitive diagnosis of diabetic neuropathy
Exclusion criteria:

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **42**
Actual sample size reached: **39**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
Both patients and and researchers did not know about type of treatment and patient grouping.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Jundishapour University of Medical Sciences, Golestan Blvd., Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
61355393
Approval date
2017-10-04, 1396/07/12

Ethics committee reference number
IR.AJUMS.REC.1396.605

Health conditions studied

1

Description of health condition studied
Painful 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 severity
Timepoint
Every week
Method of measurement
Visual analog scale (VAS)

Secondary outcomes

1

Description
Side effects
Timepoint
Every week
Method of measurement
Examination and patient history

Intervention groups

1

Description
Intervention group: Nortriptyline (25 to 75 mg)
Category
Treatment - Drugs

2

Description
Intervention group: TENS
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan Hospital
Full name of responsible person

دکتر مهنوش ذاکرکیش

Street address

Golestan Hospital, Golestan Blvd, Ahvaz

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Ahvaz

Province

Khouzestan

Postal code

6135733118

Phone

+98 61 3374 3001

Email

Zakerkish@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mehrnoosh ZakerKish

Street address

Jundishapour University of Medical Sciences, Golestan Blvd., Ahvaz

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Endocrinology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Davood Reisi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

Internal Medicine Residency

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Email

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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

Not applicable

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