Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 = 21per 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

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Iran (Islamic Republic of)

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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 مهرنوش ذاکرکیش
Street address
Golestan Hospital, Golestan Blvd, Ahvaz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
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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
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Associate professor
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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