Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effectiveness of neurodynamic techniques on neuropathy severity, tibial nerve’s conduction parameters, quality of life, straight leg raising range of motion in patients with diabetic peripheral neuropathy.

Protocol summary

Study aim

The primary objective of the present study is to investigate the effectiveness of neurodynamic techniques on diabetic neuropathy severity in patients with diabetic peripheral neuropathy.

Design

Double-blinded randomized sham controlled trial with parallel groups. Randomization will be performed with Balanced (permuted) block randomization method.

Settings and conduct

This double-blinded RCT will be performed in Physical Medicine and Rehabilitation clinic of Baqiyatallah Hospital. In this study, participants and the assessor will not be aware of the groups' allocation. Participants in control group will receive sham neurodynamic techniques in addition to basic treatments so, patients will not be aware of the groups' allocation. Data analysis will be performed by a person who is not aware of the groups' allocation.

Participants/Inclusion and exclusion criteria

Adults (18-70) who are diagnosed with mild to moderate diabetic peripheral neuropathy can participate in the present study. Those patients with severe diabetic peripheral neuropathy do not have the basic inclusion requirements.

Intervention groups

Experimental group: Basic treatment based on guidelines in this regard include TENS and Tibial nerve's massage and real tibial nerve's slider neurodynamic techniques. Control group: Basic treatment based on guidelines in this regard include TENS and Tibial nerve's massage and sham tibial nerve's slider neurodynamic techniques.

Main outcome variables

Primary outcome: The Michigan Diabetic Neuropathy Score (MDNS). Secondary outcomes: NCV, Amplitude of MNAP, distal latency, F-wave latency of tibial nerve, Neuropathy specific quality of life questionnaire, Straight leg raising range of motion.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220401054379N1**
Registration date: **2022-10-13, 1401/07/21**
Registration timing: **prospective**

Last update: **2022-10-13, 1401/07/21**
Update count: **0**

Registration date

2022-10-13, 1401/07/21

Registrant information

Name

Mahdi Ashoori

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4423 9666

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-09-11, 1402/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effectiveness of neurodynamic techniques on neuropathy severity, tibial nerve's conduction parameters, quality of life, straight leg raising range of motion in patients with diabetic peripheral neuropathy.

Public title
The effectiveness of neurodynamic techniques in diabetic peripheral neuropathy.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
1. Adults (18-70 years) diagnosed with T2DM by an expert endocrinologist based on their most recent test (within the past 3 months). 2. Patients diagnosed with diabetic peripheral neuropathy based on electrodiagnostic study that was taken by an expert physiatrist. 3. Included patients must have at least 90° hip flexion, full knee extension, and 0° dorsiflexion to 30° plantarflexion

Exclusion criteria:
1. Lasting low back pain, neck pain, and sciatalgia (at least for 3 days) in the last 6 months 2. History of chemotherapy or spinal surgery in the last year 3. History of peripheral nerves' injury or surgery 4. Alcohol or chemical addiction 5. Pregnancy 6. Syphilis, Guillain barre syndrome, rheumatoid arthritis 7. Infection or open wound in the lower limbs 8. Amputation proximal to the metatarsophalangeal joint 9. Complex regional pain syndrome 10. Tarsal tunnel syndrome 11. Severe diabetic peripheral neuropathy (30<MDNS<46) 12. Personal reluctance to paticipate in the present study

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
DPN participants will be randomized to a real NDT group or a sham NDT group with a ratio of 1:1. Block-balanced randomization technique will be used for randomization with 4 character blocks containing letters A and B. Allocation instruction will be written and will be placed in sequentially numbered, opaque, sealed envelopes. The allocation sequence will be conducted by https://www.randomizer.org/. DPN participants will be blinded to allocation schedule until the end of the study. The procedure will be performed by the impartial secretary of the Baghiyatallah physical medicine and rehabilitation clinic who will not be involved with participant assessment, allocation, or treatment. The randomization schedule is known only to the first author (MA) who is the therapist of this study. Participants will receive numbered, opaque, and sealed envelopes. The therapist who is not responsible for outcomes assessment will open these sealed envelopes and realize the participant's treatment condition. Research team members who are responsible for data collection (SEH) and data analysis (MRP) will not be permitted to be aware of group allocation.

Blinding (investigator's opinion)
Double blinded

Blinding description
This is a double-blinded trial. Participants, outcome assessor, and data analysts are all blinded regarding allocation throughout the duration of the study. Therapist will be asked not to reveal participants' allocation status during the trial.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Iran University of Medical Sciences

Street address
No. 5, Farhang Street, West Sadooghi, Ashrafiesfahani street.

City
Tehran

Province
Tehran

Postal code
1461934376

Approval date
2022-07-10, 1401/04/19

Ethics committee reference number
IR.IUMS.REC.1401.316

Health conditions studied

1

Description of health condition studied
Diabetic peripheral neuropathy

ICD-10 code
G63.2

ICD-10 code description

Polyneuropathy in diseases classified elsewhere

Primary outcomes

1

Description
The Michigan Diabetic Neuropathy Score(MDNS)
Timepoint
MDNS as the primary outcome of the present study will be evaluated before the study and at the last session.
Method of measurement
The Michigan Diabetic Neuropathy Score(MDNS)

Secondary outcomes

1

Description
Tibial nerve conduction velocity
Timepoint
Before the study and at the last session.
Method of measurement
Nerve condyution study unit (Neuropack®, s1 MEB-9400, Nihon Kohden, Japan).

2

Description
Tibial nerve's distal latency
Timepoint
Before the study and at the last session.
Method of measurement
Nerve condyution study unit (Neuropack®, s1 MEB-9400, Nihon Kohden, Japan) .

3

Description
Amplitude of motor nerve action potential
Timepoint
Before the study and at the last session.
Method of measurement
Nerve condyution study unit (Neuropack®, s1 MEB-9400, Nihon Kohden, Japan) .

4

Description
Quality of life
Timepoint
Before the study and at the last session.
Method of measurement
Persian localized version of Neuro QoL questionnaire.

5

Description
Straight leg raising range of motion.
Timepoint
Before the study and at the last session.
Method of measurement
Manual goniometer.

6

Description
F-wave latency.
Timepoint
Before the study and at the last session.
Method of measurement
Nerve condyution study unit (Neuropack®, s1 MEB-9400, Nihon Kohden, Japan) .

Intervention groups

1

Description
1. Experimental group a) Real tibial nerve’s distal slider technique: This technique will be performed in the side-lying position on the intended side. Enough pillows will support the patient’s head and neck in a comfortable and neutral position and will also assure that the thoracolumbar spine is in neutral alignment. In this position, the therapist will flex the patient’s hip to 80°, and keep the knee in full extension. Therapist will move the ankle into dorsiflexion, eversion combined with toes extension, and ask the patient to extend his or her head and neck simultaneously. b) Real tibial nerve’s proximal slider technique:This technique will be performed in the same position as explained for tibial nerve distal slider technique. In this position, the therapist will move the ankle toward plantarflexion, inversion combined with toes flexion and ask the patient to flex the head and neck simultaneously. These techniques will be performed with 10 repetition in 5 sets. Standard basic treatment: Participants will receive TENS for 20 minutes. On of the electrodes will be placed over the popliteal fossa and the other one will be placed at the medial tarsal tunnel level. On the other hand participants will receive nerve massage for tibial nerve in transverse and longitudinal order at popliteal fossa and medial tarsal tunnel for 4 minutes.
Category
Rehabilitation

2

Description
2. Control group: a) Sham tibial nerve’s distal slider technique: Patient will be asked to be in side-lying position as described for real slider techniques , but the therapist will move the patient’s hip toward abduction, flex the hip to 20°, and keep the knee in extended position. The sequence of sham tibial neurodynamic distal slider technique will be the same as the sequence of real tibial neurodynamic distal slider technique . b) Sham tibial nerve’s proximal slider technique: Participants’ starting position will be as same as the initial position of sham tibial nerve distal slider technique. The sequence of this technique will be the same as real tibial proximal slider technique. These techniques will be performed with 10 repetition in 5 sets.

Standard basic treatment: Participants will receive TENS for 20 minutes. On of the electrodes will be placed over the popliteal fossa and the other one will be placed at the medial tarsal tunnel level. On the other hand participants will receive nerve massage for tibial nerve in transverse and longitudinal order at popliteal fossa and medial tarsal tunnel for 4 minutes.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Baqiyatallah al-Azam Hospital

Full name of responsible person
Seyed Ebrahim Hashemi

Street address
Physical Medicine and Rehabilitation clinic, Seccond floor, Baqiyatallah al-Azam Hospital, Mollasadra street, Vanak square.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
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School of rehabilitation sciences Department of Physical Therapy Iran university of Medical Sciences Madadkaran All., Shahnazari St., Madar Sq., Mirdamad Blvd.

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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
Iran 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
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Seyed Ebrahim Hashemi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Physical Medicine

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Person responsible for scientific inquiries

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Assistant Professor

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Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mahdi Ashoori

Position
Physiotherapy MSc student

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

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Email
mahdiashooript@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
If it is necessary, raw data of the results of the present study will be accessible for applicants.

When the data will become available and for how long
6 months after the publication date of the original article.

To whom data/document is available
Researchers, scientists, and clinicians who are interested in this field.

Under which criteria data/document could be used
The raw data of the results of this study will be appropriate for secondary analysis in review articles, and also, can be utilized by scientists in neurodynamic or diabetic peripheral neuropathy field.

From where data/document is obtainable
If data access was required, the individual-level dataset would be available by sending a reasonable e-mail to the first corresponding author (MRP) (pourahmadipt@gmail.com).

What processes are involved for a request to access data/document
If the request is acceptable, data will be sent by an email in one week. Request email have to sent to the first corresponding author(MRP) (pourahmadipt@gmail.com).

Comments