Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effects of active and passive mobilization of tibial nerve on pain intensity and conduction velocity of tibial nerve in neuropathy of type 2 diabetic patients

Protocol summary

Study aim
Comparing the effects of active and passive mobilization of tibial nerve in neuropathy of type 2 diabetic patients

Design
Clinical trial with two parallel groups; Single-blind; Sample size will be extracted through a pilot study; Randomization: Patients are randomly assigned to one of the two groups: active or passive neurodynamics by selecting one of the sealed envelopes that are related to the determination of the groups

Settings and conduct
The work is carried out at Deziani Hospital and has two groups: active neurodynamics and passive neurodynamics. The number of treatment sessions is 15 sessions, both treatment groups receive cutaneous nerve stimulation for 20 minutes in the sole of the foot as a basic treatment. Blinding is such that patients are unaware of which treatment group they are in.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Men and women; with type 2 diabetes; in the age group of 40-75 years; passing at least 2 years since the onset of diabetes and 6 months since the onset of neuropathy symptoms (severity: grade 1 and 2 neuropathy by monofilament instrument, Michigan questionnaire and tibial nerve conduction velocity examination that is above 40 m/s); leg pain of 3 or more in the VAS scale. Exclusion criteria: diabetic foot ulcer; irritable pain; lack of cooperation or understanding in sensory testing or manual therapy; drug or alcohol dependence; lumbar disc herniation; damage to the nerves of the lower extremities; the presence of retinopathy; history of cardiovascular disease; musculoskeletal deformity

Intervention groups
Intervention group1: physiotherapist performs passive neurodynamic of tibial nerve with 10 repetitions; Intervention group 2 :active neurodynamics of the tibial nerve performed by the patient himself 10 times.

Main outcome variables
Score of Michigan questioner; quality of life questioner; pain intensity; tibial nerve conduction velocity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220216054035N2**
Registration date: **2025-08-05, 1404/05/14**
Registration timing: **prospective**

Last update: **2025-08-05, 1404/05/14**
Update count: **0**

Registration date
2025-08-05, 1404/05/14

Registrant information

Name
Monire Alem

Name of organization / entity

Country
Iran (Islamic Republic of)

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Email address
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Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-09-03, 1404/06/12

Expected recruitment end date
2026-08-23, 1405/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of active and passive mobilization of tibial nerve on pain intensity and conduction velocity of tibial nerve in neuropathy of type 2 diabetic patients

Public title

The effects of active and passive mobilization of tibial nerve in neuropathy of type 2 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Passing at least 2 years since the onset of diabetes Their leg pain is 3 or higher Their blood sugar levels are in the range of 100-250 It has been 6 months since the onset of neuropathy symptoms Men and women with type 2 diabetes In the age group of 40-75 years Grade 1 and 2 neuropathy via monofilament instrument, Michigan questionnaire, and tibial nerve conduction velocity assessment

Exclusion criteria:

Diabetic foot ulcer Irritable pain Lumbar disc herniation Damage to the nerves of the lower extremities History of cardiovascular disease Musculoskeletal deformity Lack of cooperation or understanding during sensory testing or manual therapy Dependency to drug or alcohol Lumbar disc herniation Damage to the nerves of the lower extremities Retinopathy History of cardiovascular disease

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **1**

Both feet of people

Randomization (investigator's opinion)

Randomized

Randomization description

Using the simple individual randomization method, patients who meet the study entry criteria after evaluation randomly select one of two types of sealed envelopes, corresponding to the active or passive mobilization method, and thus their type of intervention group is determined.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants are unaware of which treatment group they will be placed in. Participants in two different groups will be treated at different times so that they do not realize the differences in the treatments through observation and conversation with each other.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

No. 8, Shams Alley, before Tavanir, Valiasr Street, Tehran

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Province

Tehran

Postal code

1314744513

Approval date

2024-12-14, 1403/09/24

Ethics committee reference number

IR.SBMU.RETECH.REC.1403.513

Health conditions studied

1

Description of health condition studied

Neuropathy of diabetes

ICD-10 code

E11.40

ICD-10 code description

Type 2 diabetes mellitus with diabetic neuropathy, unspecified

Primary outcomes

1

Description

Conduction velocity of tibial nerve

Timepoint

Before intervention and end of treatment sessions (19th day)

Method of measurement

Electromyography

2

Description
Pain
Timepoint
Before intervention and end of treatment sessions (19th day)
Method of measurement
Visual analog scale (VAS)

Secondary outcomes

1

Description
Neuropathy score on the Michigan Questionnaire
Timepoint
Before intervention and end of treatment sessions (19th day)
Method of measurement
With Michigan questionnaire, this questionnaire consists of two parts: Part A,ranging from 0 to a score of 13, with a higher score indicating greater severity of neuropathy , and Part B, where a score above 2 indicates neuropathy

2

Description
Quality of life questionnaire score
Timepoint
Before intervention and end of treatment sessions (19th day)
Method of measurement
Quality of life Questionnaire with 15 questions

3

Description
Leg raising range of motion
Timepoint
Before intervention and end of treatment sessions (19th day)
Method of measurement
Goniometer

Intervention groups

1

Description
Intervention group 1: Active mobilization of tibial nerve is performed five sessions per week for 3 weeks in supervised manner. To perform the neurodynamic gliding exercise of the tibial nerve: The patient sits in a slump position. In the starting position, the neck, trunk, and knee are in flexion, the ankle is in plantar flexion and inversion, that brings the neck, trunk, and knee into extension and the ankle into dorsiflexion and eversion. This cycle lasts 4 seconds each time and we ask the patient to repeat this 10 times sitting on the bed.
Category
Rehabilitation

2

Description
Intervention group 2: passive mobilization of tibial nerve with the patient in the supine position five sessions per week for 3 weeks. Tibial nerve glide The patient is in the supine position, in the starting position the patient's knee is in extension and the ankle is in plantarflexion and inversion, and the therapist moves the ankle to dorsiflexion and eversion and the knee to flexion.Tibial nerve tension with the shock lock method: The patient is in the supine position, in the starting position the patient's knee is in flexion and the ankle is in plantarflexion and inversion, and the therapist moves the ankle to dorsiflexion and eversion and the knee to extension. This method is performed 10 times for the patient in each session.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Deziani specialized and subspecialty clinic
Full name of responsible person
Monire Alem
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Monire Alem
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Person responsible for updating data

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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

Pain intensity

When the data will become available and for how long

Six months after publication of the paper

To whom data/document is available

All people

Under which criteria data/document could be used

People that research in this field

From where data/document is obtainable

Via email: monireaalem@gmail.com

What processes are involved for a request to access data/document

Send a request via email and state for what purpose he/she need the data.

Comments