

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 Dezir 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)

Phone

+98 17 3327 5887

Email address

monireaaalem@gmail.com

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

City

Tehran

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

Street address

Deziani hospital, in front of Behesht 17, before the three-way Molaghati, Shahid beheshti street

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

Position

Doctoral student in physiotherapy

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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Other areas of specialty/work

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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: monireaaalem@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