

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Study of the Effect of Local Vibration on Balance, Protective and Vibration Sensation, Pain and Foot Temperature in Patients with Diabetic Neuropathy (before-After Clinical Trial)

Protocol summary

Study aim

To examine the effect of local foot vibration on balance, sense (protective and vibration), foot pain and foot temperature in patients with diabetic neuropathy

Design

Before-after clinical trial, lacking control group

Settings and conduct

12 Diabetic neuropathy Patients whose neuropathy was confirmed by the physician, were referred to physiotherapist from the Diabetes Center and the Metabolic Diseases of Tehran University of Medical Sciences. All assessment was done before, immediately after and after 5th session of therapy for both feet. Demography data such as age, gender, duration of disease, type of medication that patients taken, was recorded by physiotherapist. Intervention was done in rehabilitation center of Shariati hospital by physiotherapist. Data analysis was performed using ANOVA and Bonferroni in SPSS software version 22.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1-Patient with diabetic neuropathy to diagnose a doctor (Michigan score of 4 and above) 2-Age between 50-70 3-Ability to walk independently Exclusion criteria 1-Inability to complete balance test 2-Dissatisfaction to continue the plan 3-wound in the plantar side of the foot 4-Charico joint 5-suffering from other neurological disease

Intervention groups

The patient was left in crook lying with no shoes and socks on the bed and placed one pillow under the knees so that the knees are comfortable on them. Both of the feet placed on vibrator and a local vibration with a frequency of 62.5 Hz for 10 minutes was applied to the plantar side of both feet. The device was placed on the platform, which was separated from the bed. Patients referred for the five sessions a day in between, for treatment.

Main outcome variables

Balance(brief-BEST test), protective sensation (monofilament), vibration sensation(tuning fork), temperature(thermometer), pain(NPRS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190414043268N1**

Registration date: **2020-06-05, 1399/03/16**

Registration timing: **retrospective**

Last update: **2020-06-05, 1399/03/16**

Update count: **0**

Registration date

2020-06-05, 1399/03/16

Registrant information

Name

mahsa sabziparvar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

2019-08-11, 1398/05/20
Actual recruitment end date
2019-10-12, 1398/07/20
Trial completion date
2019-10-12, 1398/07/20

Scientific title
Study of the Effect of Local Vibration on Balance, Protective and Vibration Sensation, Pain and Foot Temperature in Patients with Diabetic Neuropathy (before-After Clinical Trial)

Public title
Study of the effect of local vibration on diabetic neuropathy symptoms

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having Diabetic neuropathy based on physician diagnosis (Michigan score 4 and above) Age between 50-70 Ability to walk independently
Exclusion criteria:
Wound on plantar area of foot Charcot joint Suffering from other neurological disease

Age
From **50 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **12**
Actual sample size reached: **12**

Randomization (investigator's opinion)
N/A

Randomization description
Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used

Assignment
Single

Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ethics committee of nursing and midwifery and rehabilitation Schools of Tehran University of Medical
Street address
Ghods Ave, Keshavarz blv

City
Tehran
Province
Tehran
Postal code
1419733171

Approval date
2019-06-25, 1398/04/04
Ethics committee reference number
IR.TUMS.FNM.REC.1398.060

Health conditions studied

1
Description of health condition studied
Diabetic polyneuropathy
ICD-10 code
E08.42
ICD-10 code description
Diabetes mellitus due to underlying condition with diabetic polyneuropathy

Primary outcomes

1
Description
Score of Balance Test
Timepoint
Before, at the end of the first and fifth session
Method of measurement
Brief balance evaluation system test (brief-BEST)

2
Description
Protective sensation
Timepoint
Before, at the end of the first and fifth session
Method of measurement
Monofilament (5.07)

3
Description
Threshold of vibration sensation
Timepoint
Before, at the end of the first and fifth session
Method of measurement
Rydel-Seiffer tuning fork (128 Hz)

4
Description
Foot temperature
Timepoint
Before, at the end of the first and fifth session
Method of measurement
Manual- digital thermometer

5

Description

The status of vibration sensation

Timepoint

Before, at the end of the first and fifth session

Method of measurement

Tuning fork (128 Hz)

6

Description

Pain

Timepoint

Before, at the end of the first and fifth session

Method of measurement

Numerical pain rating scale (NPRS)

Secondary outcomes

empty

Intervention groups

1

Description

The patients was left in crook lying with no shoes and socks on the bed and placed one pillow under the knees so that the knees are comfortable on them. Average room temperature was set to 25 °. Both of the feet placed on vibrator and a local vibration with a frequency of 62.5 Hz for 10 minutes was applied to the plantar side of both feet. The device was placed on the platform, which was separated from the bed. Patients referred for the five sessions a day in between, for treatment.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes and Metabolic Disease Center

Full name of responsible person

Dr Neda Mehrdad

Street address

Diabetes and Metabolic Disease Center, first cross road, Shahrivar street, North Kargar

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1411715851

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Email

emri-diabetes@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Tehran University of Medical Science

Full name of responsible person

Dr Masood younesian

Street address

Vice chancellor for research and technology of Tehran University of Medical Science, Sixth floor, university central office, at the corner of Qods street, Keshavarz 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

Vice chancellor for research of Tehran University of Medical Science

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

Department of Physiotherapy, School of Rehabilitation ,Tehran University of Medical Science

Full name of responsible person

Mahsa Sabziparvar

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Department of physiotherapy ,School of Rehabilitation , Pitch-e-Shemiran, Enghelab Ave

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only a part of the data that is related to the original outcome can be shared.

When the data will become available and for how long

Start of access period after printing results

To whom data/document is available

Medical Academic researchers

Under which criteria data/document could be used

No analytical is allowed on the data delivered.

From where data/document is obtainable

To receive data or documents connect with email sabziparvarm@yahoo.com or address: enghelab street- Piche-e-shemiran- rehabilitation faculty-physiotherapy department mahsa sabziparvar tel:09187133422

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

After receiving the requested email, it will be answered.

Comments