

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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)

##### Phone

+98 21 4497 7014

##### Email address

m\_sabziparvar@razi.tums.ac.ir

##### 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1411715851

##### Phone

+98 21 8833 4192

##### 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

##### City

Tehran

##### Province

Tehran

##### Postal code

417653761 1

##### Phone

+98 21 8163 3698

##### Fax

+98 21 8163 3654

##### Email

rcco@tums.ac.ir

#### 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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**Full name of responsible person**

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**Position**

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**Latest degree**

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**Full name of responsible person**

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**Email**

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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**