

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of transcutaneous auricular vagus nerve stimulation On lower limb nerve conduction velocity and perfusion, foot neuropathic pain and quality of life in individuals with type 2 diabetes-double blinded controlled clinical trial

#### Protocol summary

##### Study aim

Effects of transcutaneous auricular vagus nerve stimulation On lower limb nerve conduction velocity and perfusion, foot neuropathic pain and quality of life in individuals with type 2 diabetes

##### Design

The intervention consists of 12 sessions. Ten participants will be included in each group and assigned using block randomization to either the intervention or control group. recorded.

##### Settings and conduct

The intervention consists of 12 sessions. It will be administered via the concha of both ears for each participant, three times per week over a period of four weeks. This is a double-blind study: both the participants and the assessors are unaware of the group allocations. The study assessors include those performing the NCV test, ABI test, HRV test, and clinical examinations such as touch sensation, vibration, joint position sense, and balance. The person administering the intervention (electrode placement and current adjustment) and the data analyst are not blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: EMG Electrodiagnosis of diabetic neuropathy consist of small fiber neuropathy and axonal diabetic neuropathy. Distal foot pain. Pain score of 3 to 7 NPRS Exclusion criteria: Peripheral artery disease cause to foot ulcer and amputation/Pregnancy and breast feeding/Heart arrhythmia and heart battery/Spin radiculopathy and lower limb fracture

##### Intervention groups

The intervention group receives electrical stimulation on the auricular concha. The control group receives electrical stimulation on the ear lobe.

##### Main outcome variables

Pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20250602066020N1**

Registration date: **2025-06-27, 1404/04/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2025-06-27, 1404/04/06**

Update count: **0**

##### Registration date

2025-06-27, 1404/04/06

##### Registrant information

##### Name

Maryam Alizadeh Chamkhaleh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5572 7721

##### Email address

maryam.alizadeh9655@gmail.com

##### Recruitment status

**recruiting**

##### Funding source

##### Expected recruitment start date

2025-06-22, 1404/04/01

##### Expected recruitment end date

2026-06-22, 1405/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Effects of transcutaneous auricular vagus nerve stimulation On lower limb nerve conduction velocity and perfusion, foot neuropathic pain and quality of life in individuals with type 2 diabetes-double blinded controlled clinical trial

### Public title

Effects of transcutaneous auricular vagus nerve stimulation On diabetic neuropathy

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

1.Diabetic neuropathy/ 2.40 to 75 years old/ 3.Both sex/ 4.EMG Electrodiagnosis of diabetic neuropathy consist of small fiber neuropathy and axonal diabetic neuropathy /5.Hyposthesia/ 6. Distal foot pain/ 7.Pain score of 3 to 7 NPRS/ 8.Reading and writing ability

#### Exclusion criteria:

1.Non diabetic neuropathy/ 2. cigarette or alcohol usage/ 3.Peripheral artery disease cause to foot ulcer and amputation/ 4. Alternative medicine/ 5.Pregnancy and breast feeding/ 6.Heart arrhythmia and heart battery/ 7.Spin radiculopathy and lower limb fracture/ 8.Do not like to join study

### Age

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

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant
- Outcome assessor

### Sample size

Target sample size: **20**

### Randomization (investigator's opinion)

Randomized

### Randomization description

If patients meet the eligibility criteria for the study, they will be randomly assigned to either the intervention or control group using the block randomization method. Patients will be blinded to their group assignment. After conducting a pilot study and determining the final sample size, participants will be divided into blocks. All blocks will be of equal size. For example, in a two-group trial (intervention and control), blocks of 8 participants will be used, with 4 assigned to the intervention group and 4 to the control group. To determine group assignment, a die will be rolled: even numbers will place the participant in the intervention group, and odd numbers will place them in the control group.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

This study is double-blind: both the patients and the assessors are unaware of group allocation. The study assessors include the individuals performing the NCV

test, ABI test, HRV test, and clinical examinations such as touch sensation, vibration, joint position sense, and balance assessments. The person administering the intervention (electrode placement and current adjustment) and the data analyst are not blinded.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Social Welfare and Rehabilitation

##### Street address

No16, Anooshirvan Alley, Haddadi St, Qazvin St

##### City

Tehran

##### Province

Tehran

##### Postal code

1355865491

#### Approval date

2025-06-11, 1404/03/21

#### Ethics committee reference number

IR.USWR.REC.1404.056

## Health conditions studied

### 1

#### Description of health condition studied

Diabetic Neuropathic

#### ICD-10 code

E08.610

#### ICD-10 code description

Diabetes mellitus due to underlying condition with diabetic neuropathic arthropathy

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Before and After Trial

#### Method of measurement

Numeric Pain Rating Scale

## Secondary outcomes

## 1

### Description

Sural Nerve NCV

### Timepoint

Before and After Trial

### Method of measurement

NCV

## 2

### Description

Medial Plantar Nerve NCV

### Timepoint

Before and After Trial

### Method of measurement

NCV

## 3

### Description

Ankle Brachial Index

### Timepoint

Before and After Trial

### Method of measurement

Pressure Gauge

## 4

### Description

Quality of Life

### Timepoint

Before and After Trial

### Method of measurement

Questionnaire

## Intervention groups

## 1

### Description

Intervention group: Intervention will be performed via the cochlea of both ears for each participant 3 times a week for 4 weeks. Biphasic symmetrical current with a frequency of 2 Hz and a duration of 200 ms and the intensity increases to the patient's tolerance (maximum 5 mA)

### Category

Treatment - Other

## 2

### Description

Control group: will be performed via the Ear Lobe of both ears for each participant 3 times a week for 4 weeks. Biphasic symmetrical current with a frequency of 2 Hz and a duration of 200 ms and the intensity increases to the patient's tolerance (maximum 5 mA)

### Category

Treatment - Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Iranian Diabetes Society

#### Full name of responsible person

Maryam Alizadeh Cham Khale

#### Street address

No 27, Malakooti St, Patras Lumumba St, Satarkhan

#### City

Tehran

#### Province

Tehran

#### Postal code

1443914661

#### Phone

+98 21 8824 8124

#### Fax

#### Email

info@ids.org.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

University of social welfare and rehabilitation sciences

#### Full name of responsible person

Hamidreza Khankeh

#### Street address

Kodakyar Alley, Daneshjoo St, Velenjak

#### City

Tehran

#### Province

Tehran

#### Postal code

1985713871

#### Phone

+98 21 7173 2822

#### Email

rd@uswr.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

University of social welfare and rehabilitation 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**  
University of social welfare and rehabilitation sciences

**Full name of responsible person**  
Maryam Alizadeh Cham Khale

**Position**  
PHD Student

**Latest degree**  
Medical doctor

**Other areas of specialty/work**  
Physiotherapy

**Street address**  
No 16, Anoshervan Alley, Haddadi St, Qazvin St

**City**  
Tehran

**Province**  
Tehran

**Postal code**  
1355865491

**Phone**  
+98 21 5572 7721

**Email**  
Maryam.Alizadeh9655@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
University of social welfare and rehabilitation sciences

**Full name of responsible person**  
Maryam Alizadeh Cham Khale

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PHD Student

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Maryam.Alizadeh9655@gmail.com

## Person responsible for updating data

### Contact

### Name of organization / entity

University of social welfare and rehabilitation sciences

### Full name of responsible person

Maryam Alizadeh Cham Khale

### Position

PHD Student

### Latest degree

Medical doctor

### Other areas of specialty/work

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

For Patient Privacy

### 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

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

### Data Dictionary

Not applicable

### Title and more details about the data/document

Examinations and evaluations

### When the data will become available and for how long

Up to one month after the end of the study

### To whom data/document is available

Researchers and relevant officials

### Under which criteria data/document could be used

For research

### From where data/document is obtainable

By email to the scientific responsible person

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

About a week

### Comments