# 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 blined 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 blined 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
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## 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**
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**Postal code**
1985713871
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**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**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**