Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 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
Recruitment complete

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
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
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 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
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

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