Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of ear acupressure in comparison with sham control on neuropathy symptoms and quality of life in patients with type 2 diabetes

Protocol summary

Study aim
Determining the effect of ear acupressure on the symptoms of neuropathy and quality of life in patients with type 2 diabetes

Design
Clinical trial with control group, with parallel groups, single blind, randomized on 70 patients

Settings and conduct
This study is a randomized clinical trial and patients are divided into intervention and control groups based on permutation blocks. The sample size in each group is 35, the research site will be the special clinic of Shafa Hospital in Boshrouyeh. For the intervention group, ear acupressure will be performed three times a day for six weeks. In the control group, acupressure will be performed in the false point for six weeks, while patients will be unaware of being in the control or test group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patient willingness and informed written consent to participate in the study; Awareness and ability to speak and communicate; Age between 18 and 60 years; Get a minimum score of 6 on the Toronto Diabetic Neuropathy Questionnaire. Non-inclusion criteria: Taking drugs or taking strong painkillers while studying; history of disease or condition affecting neuropathy

Intervention groups
Intervention group: pressure will be applied to labels containing 5 plant seeds located in the adaptive area of the legs in the outer ear for 1 minute, 3 times a day will be done by the patient himself for 6 weeks after training. Control group: pressure is applied to the labels containing 5 plant seeds located in the adaptive area of the heart in the outer ear for 1 minute, which is applied 3 times a day for 6 weeks by the patient himself after training

Main outcome variables
Symptoms of neuropathy, quality of life

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220413054530N1**
Registration date: **2022-05-02, 1401/02/12**
Registration timing: **prospective**

Last update: **2022-05-02, 1401/02/12**
Update count: **0**

Registration date
2022-05-02, 1401/02/12

Registrant information
Name
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-05-10, 1401/02/20
Expected recruitment end date
2022-07-11, 1401/04/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The effect of ear acupressure in comparison with sham control on neuropathy symptoms and quality of life in patients with type 2 diabetes

Public title
The effect of ear acupressure on diabetes
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patient willingness and having written informed consent to participate in the study Get a minimum score of 6 on the Toronto Diabetic Neuropathy Questionnaire Awareness and ability to speak and communicate to report the severity of clinical symptoms during the examination Age between 18 to 60 years Having a natural earlobe
Exclusion criteria:
History of disease or condition affecting neuropathy based on medical history and patient report The presence of any known complication and other medical problem leads to pain Existence of a lesion or skin problem in the area of the ear and the site of acupressure
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, patients with diabetes referred to a special clinic in Boshrouyeh, affiliated to Birjand University of Medical Sciences, will be selected by an accessible and purposeful method based on inclusion criteria and then randomly divided into four groups of intervention and control by blocks of size 4. In this way, a list of 6 expected blocks (AABB, ABAB, BABA, ABBA, BAAB, BBAA) has been prepared and by assigning a number to each block (from 1 to 6) by throwing the dice, the blocks are randomly selected and the necessary allocation is made. This process will continue until the sample size is completed. (A for the experimental group and B for the control group)
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, participants will be randomly assigned to one of two control or test groups and will be unaware of which group they are in. For blinding in the control group, ear acupressure labels similar to the experimental group will be used, with the difference that in the control group, these labels will be used in places that will not have an effect on improving patients' neuropathy.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Gonabad University of Medical Sciences
Street address
Vice Chancellor for Research and Technology, Gonabad University of Medical Sciences, Asian Roadside, Gonabad - Khorasan Razavi
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Approval date
2022-04-11, 1401/01/22
Ethics committee reference number
IR.GMU.REC.1401.002

Health conditions studied

1

Description of health condition studied
Diabetic neuropathy
ICD-10 code
G99.0
ICD-10 code description
Autonomic neuropathy in diseases classified elsewhere

Primary outcomes

1

Description
Symptoms of neuropathy include pain and sensory disturbances (including burning, numbness, tingling, weakness, muscle cramps)
Timepoint
Beginning of the study (before the intervention) and after the intervention (six weeks after the intervention)
Method of measurement
Neuropathy Symptom Score

Secondary outcomes

1

Description
quality of life
Timepoint
At the beginning of the study (before the intervention) and six weeks after the start of the study
Method of measurement
Neuropathy specific quality of life

Intervention groups

1

Description
Intervention group: For patients in this group, in addition to the patient's routine medical care for acupressure, pressure is applied to the labels containing 5 plant seeds (which are used to form labels and the type of plant used has no effect on acupressure) located in the adaptive area of the legs in the ear. The external will be used for 1 minute (the pressure will be to the extent that the patient feels it but does not cause pain and discomfort) 3 times a day (every 8 hours) for 6 weeks by the patient after training.
Category
Other

2

Description
Control group: In this group, in addition to the patient's routine medical care, pressure is applied to the labels containing 5 plant seeds located in the adaptive area of the heart (which has no effect on patients' neuropathy) in the outer ear for 1 minute, which is 3 times. It is performed around the clock (every 8 hours) for 6 weeks by the patient himself after training.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Special clinic of Shafa Hospital
Full name of responsible person
Ali Mohammd Ali nia
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Shafa Hospital; Jihad Blvd; Boshrouyeh
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Sponsors / Funding sources

1

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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
Gonabad University of Medical 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
Gonabad University of Medical Sciences
Full name of responsible person
Ali mohammad ali nia
Position
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Latest degree
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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available