

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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

Ali Mohammadalinia

Name of organization / entity

Country

Iran (Islamic Republic of)

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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		Used
Public title	The effect of ear acupressure on diabetes	Assignment
Purpose	Supportive	Parallel
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	Other design features
Age	From 18 years old to 60 years old	Secondary Ids
Gender	Both	empty
Phase	N/A	Ethics committees
Groups that have been masked	Participant	<u>1</u>
Sample size	Target sample size: 70	Ethics committee
Randomization (investigator's opinion)	Randomized	Name of ethics committee
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)	Ethics Committee of Gonabad University of Medical Sciences
Blinding (investigator's opinion)	Single blinded	Street address
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.	Vice Chancellor for Research and Technology, Gonabad University of Medical Sciences, Asian Roadside, Gonabad - Khorasan Razavi
Placebo		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
		<u>1</u>
		Description of health condition studied
		Diabetic neuropathy
		ICD-10 code
		G99.0
		ICD-10 code description
		Autonomic neuropathy in diseases classified elsewhere
		Primary outcomes
		<u>1</u>
		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 Mohammdd Ali nia

Street address

Shafa Hospital; Jihad Blvd; Boshrouyeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Leila Sadegh Moghadam

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Vice Chancellor for Research and Technology,
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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

Student

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