Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Investigating the effect of acupuncture on the symptoms of diabetes-related peripheral neuropathy (DPN).

Protocol summary

Study aim
Determination of the effect of acupuncture on the symptoms of diabetes-related peripheral neuropathy (DPN).

Design
The clinical trial with two groups (intervention and control), pragmatic, one-blind, randomized

Settings and conduct
This study will be conducted to evaluate the effect of acupuncture on the symptoms of diabetes-related peripheral neuropathy (DPN) in a specialized clinic of Vasesi Hospital in Sabzevar. Patients will be randomly assigned to the intervention and placebo group. Pain evaluation is done by using a visual analog scale measurement scale for the study groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with their neuropathy are caused by type 1 and type 2 diabetes, Patients with a pain score of 3 or more are in the form of an assessment of the visual scale of the pain, Patients aged 40 to 60 years, Patients with at least 10 years of diabetes.
Exclusion criteria: Patients with a diabetic foot ulcer, Patients who drink alcohol or use tobacco, Patients who use immunosuppressive drugs have interfered with the interpretation of results, Patients whose neuropathy is caused by other disorders, such as carpal tunnel syndrome, AIDS, etc., Unwillingness to complete questionnaires and do acupuncture.

Intervention groups
Intervention group: In addition to routine therapies, will be treated with real acupuncture as a complementary therapy for seven sessions and once a week for 20 minutes each session. These points are marked with standard stainless needles and stimulated for 20 minutes manually for acupuncture stimulation elicits (DEQI).
Control group: The control group will only be treated under the usual treatment of neuropathy and sham acupuncture for seven sessions and once a week. And points are at least 1.5 centimeters away from the 9 main real acupuncture points will be used.

Main outcome variables
Determine the amount of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181006041252N13**
Registration date: **2019-06-27, 1398/04/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-27, 1398/04/06**
Update count: **0**

Registration date
2019-06-27, 1398/04/06

Registrant information

Name
Mohammad Sahebkar

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-26, 1398/04/05

Expected recruitment end date
2019-08-27, 1398/06/05

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of acupuncture on the symptoms of diabetes-related peripheral neuropathy (DPN).

Public title

The effect of acupuncture on the symptoms of diabetes-related peripheral neuropathy (DPN).

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with their neuropathy are caused by type 1 and type 2 diabetes Patients with a pain score of 3 or more are in the form of an assessment of the visual scale of the pain. Patients aged 40 to 60 years. Patients with at least 10 years of diabetes.

Exclusion criteria:

Patients with diabetic foot ulcer Patients who drink alcohol or use tobacco. Patients who use immunosuppressive drugs have interfered with the interpretation of results. Patients whose neuropathy is caused by other disorders, such as carpal tunnel syndrome, AIDS, etc. Unwillingness to complete questionnaires and do acupuncture

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was conducted based on a permutation block by a statistical consultant using random allocation software and the output sequences A and B are available to the researcher, Accordingly, 13 blocks were allocated to patients, in each block, 2 from A treatment group, 2 from the B treatment group were placed. Eventually, after completing the blocks group A was treated with Group A is treated with acupuncture and Group B is being treated with placebo (sham acupuncture). First, we determine all sixsome modes in which two individuals are assigned to group A and two to group B. Then we assign one of the digits 1 to 6 to each of the sixsome combinations (which includes thirty-six modes). In the next step, we must randomly select 13 blocks of six and write their combinations in succession. For this we have to make 13 samplings with replacement from a six-member community; 6 times, choose a random number between 1 and 6 and this process will continue until the end of the sampling and the difference between the two groups will not exceed a maximum of two (half the size of the block).

Blinding (investigator's opinion)

Single blinded

Blinding description

Each person in the study will be assigned code A and B, that the researcher will only be known of the type of groups. Participants are unaware of the groups. It should be noted that acupuncture and placebo (sham acupuncture) are similar in appearance, color, and packaging.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Sabzevar University of Medical Sciences, Tohid Blvd, Sabzevar city

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Approval date

2019-06-15, 1398/03/25

Ethics committee reference number

IR.MEDSAB.REC.1398.023

Health conditions studied

1

Description of health condition studied

Diabetes-related peripheral neuropathy (DPN).

ICD-10 code

E08.40

ICD-10 code description

Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified

Primary outcomes

1

Description

Determine the amount of pain

Timepoint

Measuring the amount of pain at the beginning of the

study (before the intervention) and at the end of each session for seven sessions (weekly) after the start of the intervention.

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

1

Description

Determine fatigue

Timepoint

Fatigue measurement at the beginning of the study (before the intervention) and at the end of each session for seven sessions (weekly) after the start of the intervention.

Method of measurement

Multidimensional Fatigue Inventory-20= MFI-20

Intervention groups

1

Description

Intervention group: The treatment group, in addition to routine therapies, will be treated with real acupuncture as a complementary therapy for seven sessions and once a week for 20 minutes each session. Treatment in this group will be in 9 specific areas of the body. These points are marked with standard stainless needles (0.3 mm diameter, 40 mm length, Korea) and stimulated for 20 minutes manually for acupuncture stimulation elicits (DEQI). During the study period, each week will be evaluated for the improvement of neuropathy symptoms.

Category

Treatment - Other

2

Description

Control group: The control group will only be treated under the usual treatment of neuropathy and sham acupuncture. Acupuncture will be unrealistic for seven sessions and once a week. In this study, we will use the Streitberger devices. The needle is not fixed inside the copper cloth and the tip is blunt, and when it touches the skin, the feeling of itching is felt in the patient (simulating skin piercing). For the sham acupuncture group, points that are at least 1.5 centimeters away from the 9 main real acupuncture points will be used. During the study period, each week will be evaluated for the improvement of neuropathy symptoms.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Vasei hospital

Full name of responsible person

Mohammad Sahebkar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person
Mohammad Sahebkar
Position
Consultant
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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
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available