

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of local magnetic therapy on clinical symptoms of peripheral neuropathy in patients with diabetes type 2

Protocol summary

Study aim

Determining the effect of local magnetic therapy on clinical symptoms of peripheral neuropathy in patients with type 2 diabetes

Design

A randomised, double-blind, sham controlled clinical trial with a parallel group design of 64 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 32 and the research site will be the diabetes clinic of Alavi hospital in Mashhad. For the intervention group, magnetic therapy will be used 24 hours a day for 12 weeks. In the control group, the magnet which is completely similar to the intervention group without magnetic properties, will be used at the same time. Patients, the main researcher and the physician in charge of patient care and the person analyzing the data will not to know the nature of the real or neutral magnet, as well as the group position of the patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diabetic peripheral neuropathy at least 6 scores on score Neuropathy disability score (NDS) without Neuropathy symptoms score (NSS) or 3-5 scores on NDS with at least 5 scores on NSS Drug-refractory neuropathic pain intensity at least 1 score on Visual analogue scale Aged 18-70 years (either sex) Exclusion criteria: Pregnancy, planning a pregnancy, lactation

Intervention groups

Patients in the intervention group will use a magnet with an intensity of 155 mT for local magnetic therapy. The magnet at the end of the tibial nerve pathway in the lower leg, around the ankle, will be used 24 hours a day for 12 weeks. In the control group, a magnet of the same size and shape but neutralized and without magnetic properties will be used at the same place and time

Main outcome variables

Clinical symptoms of neuropathy

General information

Reason for update

To add study results and final changes

Acronym

IRCT registration information

IRCT registration number: **IRCT20210315050706N1**

Registration date: **2021-03-16, 1399/12/26**

Registration timing: **prospective**

Last update: **2024-01-04, 1402/10/14**

Update count: **1**

Registration date

2021-03-16, 1399/12/26

Registrant information

Name

Armin Nazeri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 5027

Email address

nazeri.a.stu@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-27, 1400/01/07

Expected recruitment end date

2021-04-27, 1400/02/07

Actual recruitment start date

2021-04-20, 1400/01/31

Actual recruitment end date

2021-08-06, 1400/05/15

Trial completion date

2021-11-06, 1400/08/15

Scientific title

The effect of local magnetic therapy on clinical symptoms of peripheral neuropathy in patients with diabetes type 2

Public title

The effect of local magnetic therapy on the clinical symptoms of peripheral neuropathy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Diabetes type 2; diagnosed by a diabetologist according to American Diabetes Association (ADA) standards
Diabetic peripheral neuropathy at least 6 scores on the Neuropathy disability score (NDS) without Neuropathy Symptoms score (NNS) or 3-5 scores on NDS with at least 5 scores on NSS Drug-refractory neuropathic pain intensity at least 1 score on Visual analogue scale Able to complete questionnaires and willing to sign written informed consent Aged 18-70 years (either sex)

Exclusion criteria:

Pregnancy, planning a pregnancy, lactation Had any of the following: Vascular insufficiency, Renal failure, Metallic implantation, Skin diseases, Foot ulcers, Prosthesis, Prior magnetic therapy, Cardiac pacemaker, Mechanical insulin pump or any electronic device Had diabetic peripheral neuropathy from other causes than diabetes (according to the medical history and diagnosis of specialist doctors) Opiate or drug abuse

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **64**

Actual sample size reached: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

The research units will be selected from the people referring to the hospital clinic in a purposive sampling method by considering the inclusion criteria. Then they will be assigned to the two intervention and control groups using the four-shift block method. In this way, the letter "A" will be considered for the intervention group, and the letter "B" will be considered for the control group. The possible states in the quadruple block are six states, each state will be written on a card and the cards will be assigned the numbers one to six. Then, using the dice, one of the six possible states will be selected and the selected patients will be divided into two groups. This process will continue until the sample size is completed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, as well as the corresponding author, the outcome evaluator, the data analyst, and the physician in charge of patient care, became unaware of the group position of patients, as well as the nature of the wristband containing the real or neutral magnet.

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, Khorasan
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Postal code

9691793718

Approval date

2021-03-15, 1399/12/25

Ethics committee reference number

IR.GMU.REC.1399.132

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**

Severity of clinical symptoms of diabetic neuropathy

Timepoint

At the beginning of the study and 4, 8 and 12 weeks after the start of the intervention

Method of measurement

Secondary outcomes

1

Description

Severity of neuropathic pain

Timepoint

The beginning of the study and weeks 4, 8 and 12

Method of measurement

Visual analogue scale questionnaire

2

Description

Severity of neuropathy disability

Timepoint

The beginning of the study and the 12th week after the start of the intervention

Method of measurement

neuropathy disability score questionnaire

3

Description

Quality of life

Timepoint

The beginning of the study and the 12th week after the start of the intervention

Method of measurement

NeuroQol questionnaire

Intervention groups

1

Description

Intervention group: For patients in this group for local magnetic therapy, a leather wristband with a neodymium bipolar magnet with an average magnetic intensity of 155 mTesla in the size of 15 x 3 mm will be used. The wristband at the end of the tibial nerve pathway in the lower of the leg, around the ankle, will be used continuously 24 hours a day for 12 weeks.

Category

Treatment - Devices

2

Description

Control group: In this group, the same wristband and magnet with the same size and shape will be used at the same time, with the difference that the magnet used in this group is neutral and does not have magnetic properties. The wristband at the end of the tibial nerve pathway in the lower of the leg, around the ankle, will be used continuously 24 hours a day for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alavi hospital diabetes clinic

Full name of responsible person

Armin Nazeri

Street address

Alavi hospital, Emam Reza 61 Alley, Emam Reza Ave, Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Ali Mohammadpour

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Grant name

This research was supported by a grant from Gonabad University of Medical Sciences.

Grant code / Reference number

630

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

Armin Nazeri

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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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**

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent FormUndecided - It is not yet known if there will be a plan to
make this available**Clinical Study Report**

Yes - There is 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

Title and more details about the data/document

There is no more information

When the data will become available and for how long

There is no more information

To whom data/document is available

There is no more information

Under which criteria data/document could be used

There is no more information

From where data/document is obtainable**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Armin Nazeri

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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There is no more information
What processes are involved for a request to access data/document

There is no more information
Comments

Trial results

Please tick if results have been published

Yes

Summary result posting date

2024-01-04, 1402/10/14

Table of baseline comparison

Participant flow diagram

Table of variable outcomes' results

Table of adverse events

First publication date

2023-07-04, 1402/04/13

Abstract of published paper

Background: Diabetic peripheral neuropathy (DPN) is a common complication of diabetes mellitus (DM) that can cause annoying symptoms. To address this condition, several treatment approaches have been proposed, including static magnetic field (SMF) therapy, which has shown promise in treating neurological conditions. Therefore, this study aimed to investigate the effects of SMF therapy on symptomatic DPN and the quality of life (QoL) in patients with type 2 diabetes. Methods: A double-blind, randomized, placebo-controlled trial was conducted from April to October 2021. Sixty-four DPN patients (20 males, 44 females) were recruited for the study via invitation. The participants were divided into two groups: the magnet group, which used magnetic ankle bracelets (155mT) for 12 weeks, and the sham group, which used non-magnetic ankle bracelets for the same duration. Neuropathy Symptom Score (NSS), Neuropathic Disability Score (NDS), and Visual Analogue Scale (VAS) were used to assess neuropathy symptoms and pain. In addition, the Neuropathy Specific Quality of Life Questionnaire (Neuro-QoL) tool was used to measure the patients' quality of life. Results: Before treatment, there were no significant differences between the magnet and sham groups in terms of the NSS scores ($P=0.50$), NDS scores ($P=0.74$), VAS scores ($P=0.17$), and Neuro-QoL scores ($P=0.82$). However, after 12 weeks of treatment, the SMF exposure group showed a significant reduction in NSS scores ($P<0.001$), NDS scores ($P<0.001$), VAS scores ($P<0.001$), and Neuro-QoL scores ($P<0.001$) compared to the baseline. The changes in the sham group, on the other hand, were not significant. Conclusion: According to obtained data, SMF therapy is recommended as an easy-to-use and drug-free method for reducing DPN symptoms and improving QoL in diabetic type-2 patients.