

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of Low-level laser therapy and Transcutaneous Electrical Nerve Stimulation for Treating Diabetic peripheral Neuropathy

Protocol summary

Study aim

Comparison of the efficacy of low-power laser therapy and transcutaneous electrical nerve stimulation in the treatment of diabetic peripheral neuropathy

Design

An open-label randomized clinical trial study with parallel groups and phases 3 on 60 diabetic patients with diabetic neuropathy. Randomization will be done with the block randomization method using Random allocation software.

Settings and conduct

This study will be conducted on patients with diabetic neuropathy hospitalized in Urmia Imam Khomeini Hospital. Patients will be divided into three groups: routine treatment, routine treatment combined with low-level laser therapy, and routine treatment combined with transcutaneous electrical nerve stimulation. The study will be conducted as open-label clinical trial.

Participants/Inclusion and exclusion criteria

In this study, 60 type 1 or types 2 diabetic patients with diabetic neuropathy who have been treated with conventional pharmacotherapy for at least three months will be enrolled. Major exclusion criteria for patients include other lower limb problems and diseases, history of any lower limb amputation, lower limb trauma, and history of stroke.

Intervention groups

Patients will be randomly divided into three groups: 1- Group one: the conventional treatment method will continue (without receiving any new intervention); Group two: the conventional treatment method combined with low-power laser therapy; and Group three: the conventional treatment method combined with transcutaneous electrical nerve stimulation.

Main outcome variables

Clinical signs of neuropathy; nerve conduction velocity; neuropathic motor potential latency.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230910059395N2**

Registration date: **2025-02-03, 1403/11/15**

Registration timing: **prospective**

Last update: **2025-02-03, 1403/11/15**

Update count: **0**

Registration date

2025-02-03, 1403/11/15

Registrant information

Name

Ebrahim Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-02-19, 1403/12/01

Expected recruitment end date

2025-08-22, 1404/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Low-level laser therapy and Transcutaneous Electrical Nerve Stimulation for Treating Diabetic peripheral Neuropathy		Ethics Committee of Urmia University of Medical Sciences	
Public title		Street address	
Comparison of Low-level laser therapy and Transcutaneous Electrical Nerve Stimulation for Treating Diabetic peripheral Neuropathy		Imam Khomeini hospital., Modarres Blvd., Ershad Ave.	
Purpose		City	
Treatment		Urmia	
Inclusion/Exclusion criteria		Province	
Inclusion criteria:		West Azarbaijan	
Type 2 or type 1 diabetes with at least 5 years of diabetes history Having diabetic neuropathy of the lower extremities with a confirmed diagnosis by a neurologist Patients treated with conventional pharmacotherapy methods (including gabapentin, pregabalin, duloxetine, TCAs, and other drugs) for at least three months		Postal code	
Exclusion criteria:		57157-89397	
Other lower limb problems and diseases History of any lower limb amputation Lower limb trauma Stroke history		Approval date	
Age		2024-12-11, 1403/09/21	
No age limit		Ethics committee reference number	
Gender		IR.UMSU.REC.1403.274	
Both		Health conditions studied	
Phase		1	
3		Description of health condition studied	
Groups that have been masked		Diabetic neuropathy	
No information		ICD-10 code	
Sample size		E13.4	
Target sample size: 60		ICD-10 code description	
Randomization (investigator's opinion)		Other specified diabetes mellitus with neurological complications	
Randomized		Primary outcomes	
Randomization description		1	
Patients will be divided into intervention and control groups using block randomization based on generated numbers by Random allocation software. Thus, in this software, first the number of groups and the total number of the sample size (60 patients) will be entered, and then in the block section, the Block randomization method will be selected. Patients will be allocated in intervention or control groups based on generated numbers.		Description	
Blinding (investigator's opinion)		Clinical symptoms (pain and heat, pressure sensation (monofilament), position, superficial and deep touch, paraesthesia, anesthesia, lower limb pulse)	
Not blinded		Timepoint	
Blinding description		Before and 6 weeks after the intervention	
Placebo		Method of measurement	
Not used		Clinical examination based on expert opinion	
Assignment		2	
Parallel		Description	
Other design features		Motor nerve conduction velocity	
		Timepoint	
		Before and 6 weeks after the intervention	
		Method of measurement	
		Nerve and leg muscle stripe test	
		3	
		Description	
		Neuropathic motor potential	
		Timepoint	
		Before and 6 weeks after the intervention	
		Method of measurement	
		Nerve and leg muscle stripe test	
Secondary Ids		Secondary outcomes	
empty			
Ethics committees			
1			
Ethics committee			
Name of ethics committee			

1

Description

Neuropathic sensory potential amplitude

Timepoint

Before and 6 weeks after the intervention

Method of measurement

Nerve and leg muscle strip test

Intervention groups

1

Description

Control group: The conventional treatment method will continue (without receiving any new intervention)

Category

Treatment - Drugs

2

Description

Intervention group: Second group: The conventional treatment method combined with low-power laser therapy, which duration of the laser therapy will be 6 weeks (12 sessions), with 2 sessions of 30-minute per week. The laser therapy device is Icoone Laser Med Italy (2022).

Category

Treatment - Other

3

Description

Intervention group: Third group: Conventional treatment method combined with transcutaneous electrical nerve stimulation, the duration of treatment will be 6 weeks (12 sessions), with 2 sessions of 15-minute per week based on modulated type.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Dr. Ebrahim Mohhamadi

Street address

Imam Khomeini hospital., Ershad Ave., Modarres Blvd.

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mohammadi.e@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr.Saber Gholizadeh

Street address

Urmia University of Medical Sciences., Resalat Ave.,
Jahad Blvd., Urmia, Iran.

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Ebrahim Mohammadi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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

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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 further information available.

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

Not applicable

Data Dictionary

Not applicable