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)

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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

Public title
Comparison of Low-level laser therapy and Transcutaneous Electrical Nerve Stimulation for Treating Diabetic peripheral Neuropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
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
Exclusion criteria:
Other lower limb problems and diseases History of any lower limb amputation Lower limb trauma Stroke history
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
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.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Urmia University of Medical Sciences
Street address
Imam Khomeini hospital., Modarres Blvd., Ershad Ave.
City
Urmia
Province
West Azarbaijan
Postal code
57157-89397
Approval date
2024-12-11, 1403/09/21
Ethics committee reference number
IR.UMSU.REC.1403.274

Health conditions studied

1

Description of health condition studied
Diabetic neuropathy
ICD-10 code
E13.4
ICD-10 code description
Other specified diabetes mellitus with neurological complications

Primary outcomes

1

Description
Clinical symptoms (pain and heat, pressure sensation (monofilament), position, superficial and deep touch, paraesthesia, anesthesia, lower limb pulse)
Timepoint
Before and 6 weeks after the intervention
Method of measurement
Clinical examination based on expert opinion

2

Description
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 outcomes

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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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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gholizadeh.s@umsu.ac.ir
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 Mohammmadi
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Imam Khomeini hospital., Ershad Ave., Modarres Blvd.
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Person responsible for updating data

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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