Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the therapeutic effects of high-power laser therapy and routine physiotherapy on pain and quality of life in patients with diabetic polyneuropathy

Protocol summary

Study aim

Comparison of the Effectiveness of High-Power Laser Therapy and Routine Physiotherapy in Reducing Pain Intensity, Improving Sensory and Motor Nerve Conduction Velocity, and Enhancing Quality of Life in Patients With Diabetic Peripheral Neuropathy After Four Weeks of Intervention

Design

A randomized, non-blinded, controlled clinical trial with parallel groups will be conducted on 159 patients.

Settings and conduct

This single-blind randomized trial uses convenience sampling of diabetic patients from two Tehran hospitals and assigns them by block randomization to high-power laser therapy, physiotherapy, or pharmacological treatment, with outcomes evaluated by a blinded assessor.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Diabetic patients with clinically confirmed diabetic neuropathy Exclusion criteria:Patients with type 1 diabetesPatients with fractures or joint injuriesPatients with vascular abnormalities other than diabetes mellitusPatients with radiculopathyPatients with neuropathy due to causes other than diabetesPatients with diabetic foot ulcersPatients with limb ischemiaPatients with limb venous thrombosisPatients with limb cellulitis or ulcersPatients with autoimmune diseases, vasculitis, or Raynaud’s phenomenon.

Intervention groups

Group 1 (HPLT): Class IV laser, 10W, 980nm, 6-8 J/cm², 10-15 min/limb, 12 sessions (3×week×4 weeks).Group 2 (Routine physiotherapy): 20 min heat + TENS + 1MHz US + hamstring/gastroc stretching (3×10×20s), 12 sessions.Group 3 (Control): Gabapentin 300mg nightly + B1 300mg daily, 4 weeks.

Main outcome variables

Pain intensity score based on Visual Analog Scale (VAS); Quality of life score based on Norfolk QOL-DN questionnaire; Peripheral neuropathy assessment score based on Michigan Neuropathy Screening Instrument (MNSI); Pin-prick sensory test results of the lower limbs.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251008067547N1**
Registration date: **2026-05-13, 1405/02/23**
Registration timing: **prospective**

Last update: **2026-05-13, 1405/02/23**
Update count: **0**

Registration date

2026-05-13, 1405/02/23

Registrant information

Name

Mahdie Heidaryan

Name of organization / entity

Country

Iran (Islamic Republic of)

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dyana21h@yahoo.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-05-22, 1405/03/01

Expected recruitment end date

2027-05-20, 1406/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic effects of high-power laser therapy and routine physiotherapy on pain and quality of life in patients with diabetic polyneuropathy

Public title

Comparison of the therapeutic effects of high-power laser therapy and routine physiotherapy on pain and quality of life in patients with diabetic polyneuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with type 2 diabetes and confirmed diabetic peripheral neuropathy based on clinical criteria (sensory-motor symptoms in the lower limbs), pin-prick test, and significant pain score on the VAS scale, whose diabetic medication (oral/insulin) has been stable without major dose changes for at least 3 months, have quality of life impairment related to Michigan Neuropathy Screening Instrument (MNSI) and Norfolk QOL-DN questionnaires, possess independent mobility capability and regular attendance at treatment sessions, and provide written informed consent, are eligible for study entry (no age restriction)

Exclusion criteria:

Type 2 diabetes mellitus Confirmed diabetic peripheral neuropathy based on clinical criteria Sensory-motor symptoms in the lower limbs.Positive pin-prick test result Significant pain score on VAS scale Impaired quality of life on Michigan Neuropathy Screening Instrument (MNSI).Impaired quality of life on Norfolk QOL-DN questionnaire Independent mobility capability (with/without simple assistive device).Ability to attend 12 treatment sessions regularly

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **159**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, sampling will be conducted using a non-probability convenience sampling method from the population of diabetic patients referred to Imam Hossein Hospital and Loghman Hakim Hospital in Tehran. After meeting the inclusion criteria, participants will be assigned to three intervention groups using the Simple Randomization method.In this method, each participant is randomly allocated to one of the groups using randomly 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

Research Ethics Committees of Vice-Chancellor in Research Affairs - Shahid Beheshti University of Me

Street address

Research Ethics Committees of Vice-Chancellor in Research Affairs - Shahid Beheshti University of Medical Sciences - koodakyar Ave. Daneshju Bolivar, Velenjak. Tehran, Iran

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Postal code

1985717443

Approval date

2026-01-27, 1404/11/07

Ethics committee reference number

IR.SBMU.MSP.REC.1404.716

Health conditions studied

1

Description of health condition studied

diabetic polyneuropathy

ICD-10 code

E11.42

ICD-10 code description

Type 2 diabetes mellitus with diabetic polyneuropathy

Primary outcomes

1

Description

Pain intensity score measured by Visual Analog Scale (VAS)

Timepoint

At the begining of the study and four weeks after the interventions

Method of measurement

Clinical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The high-power laser group will undergo treatment for 4 weeks, consisting of 12 sessions (3 sessions per week), using a Class IV high-power laser device with a power of 10 watts, a wavelength of 980 nanometers, and a dose of 6–8 joules per square centimeter. The laser will be applied along the course of the posterior tibial and common peroneal nerves, with each session lasting 10 to 15 minutes per limb.
Category
Other

2

Description
Intervention group: The routine physiotherapy group will undergo treatment for 4 weeks, consisting of 12 sessions (3 sessions per week). Each session will include 20 minutes of superficial heat using an infrared device or heating pad, conventional TENS (Transcutaneous Electrical Nerve Stimulation)applied to the affected nerve based, ultrasound therapy with a frequency of 1 MHz, and stretching exercises for the hamstring and gastrocnemius-soleus muscles performed in 3 sets of 10 repetitions, with each stretch held for 20 seconds.
Category
Other

3

Description
Control group: The control group will receive only pharmacological treatment, consisting of gabapentin capsules (300 mg) taken nightly and vitamin B1 tablets (300 mg) taken daily for a duration of 4 weeks.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Zahra Ebrahimabadi
Street address
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2

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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dean.medicalschool@sbmu.ac.ir
Web page address
https://www.sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mehdie Heidaryan

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

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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