Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effects of low-level laser therapy in addition to conventional physical therapy on pain and numbness of lower limb in patients with diabetic peripheral neuropathy: a randomized controlled trial

Protocol summary

Study aim
To determine the effects of Low-Level Laser Therapy in addition to conventional physical therapy on pain and numbness in lower limbs of patients with diabetic peripheral neuropathy.

Design
A concealed, randomized, single blinded, sham controlled clinical trial with a parallel group design of 43 patients, enrolled between November 2021 and March 2022, and followed for 6 months.

Settings and conduct
Physical Therapy Department, University of Lahore Teaching Hospital

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Both males and females; Age ranging from 45 to 70 years; Type II diabetes with clinical stage N2a of diabetic peripheral neuropathy; Peripheral neuropathic symptoms lasting for ≥ 6 months. Exclusion Criteria: Unstable glycemic index; Pregnancy; Some surgical cases such as knee replacement or any spinal surgery; Spinal stenosis, spinal compression or any other relative radiculopathy; Patients having malignancy and who have received radiotherapy treatment during last six months; Peripheral vascular disease or claudication; Skin discoloration or skin ulcers

Intervention groups
In experimental group, patients will receive 20-25 minutes of therapy session including 5 minutes of LLLT on lumbosacral area and plantar surface of foot each, along with the conventional therapy, including TENS for 15 minutes on lumbosacral area and plantar surface of foot. TENS will be used on both sites at the same time. This session will be given for 4 days a week, for 4 consecutive weeks. The patients in conventional physical therapy group will also receive the same treatment including TENS and LLLT but the laser unit will be switched off this time to get sham therapy.

Main outcome variables
Pain Numbness

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210702051760N1**
Registration date: **2022-03-29, 1401/01/09**
Registration timing: **retrospective**

Last update: **2022-03-29, 1401/01/09**
Update count: **0**

Registration date
2022-03-29, 1401/01/09

Registrant information

Name
Shahzaib Anwer

Name of organization / entity
The University of Lahore

Country
Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-26, 1400/05/04

Expected recruitment end date
2022-03-26, 1401/01/06

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of low-level laser therapy in addition to conventional physical therapy on pain and numbness of lower limb in patients with diabetic peripheral neuropathy: a randomized controlled trial

Public title
Effects of low-level laser therapy in addition to conventional physical therapy on pain and numbness
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Both males and females Age ranging from 45 to 70 years Type II diabetes with clinical stage N2a of diabetic peripheral neuropathy Peripheral neuropathic symptoms lasting for ≥ 6 months
Exclusion criteria:
Unstable glycemic index Pregnancy Some surgical cases such as knee replacement or any spinal surgery Spinal stenosis, spinal compression or any other relative radiculopathy Patients having malignancy and who have received radiotherapy treatment during last six months Peripheral vascular disease or Claudication Skin discoloration or skin ulcers
Age
From **45 years** old to **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant

Sample size
Target sample size: **43**
Randomization (investigator's opinion)
Randomized
Randomization description
Computer generated randomization assignments will be designed by an independent statistician and randomization will be done by one of the research team members who will not involve in patient recruitment or assessment or data analysis. The computer will randomly place the participants into control group and experimental group. The randomization assignments will be kept in opaque, sealed envelopes and unsealed by a researcher after baseline testing. Outcome assessors will be unaware of group assignment. The experiment will be started on the day after randomization.
Blinding (investigator's opinion)
Single blinded
Blinding description
Only the participants will be blinded. As both groups will be treated in prone lying and both, the participant and the care provider, will be wearing laser protection goggles, the participants will not be able to identify whether the laser probe is emitting any rays or not.
Placebo
Used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of The University of Lahore
Street address
1-Km Defence Road, near Bhuptian Chowk,
City
Lahore
Postal code
54000
Approval date
2021-11-15, 1400/08/24
Ethics committee reference number
IRB-UOL-FAHS/990/2021

Health conditions studied

1

Description of health condition studied
Diabetic Peripheral Neuropathy
ICD-10 code
E08.40
ICD-10 code description
Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified

Primary outcomes

1

Description
Pain
Timepoint
Before intervention, after 2 weeks and after 4 weeks of intervention
Method of measurement
Visual Analogue Scale for Pain

2

Description
Numbness
Timepoint
Before intervention, after 2 weeks and after 4 weeks of intervention
Method of measurement
Michigan Neuropathy Screening Instrument (MNSI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In experimental group, patients will receive 20-25 minutes of therapy session including 5 minutes of LLLT on lumbosacral area and plantar surface of foot each, along with the conventional therapy, including TENS for 15 minutes on lumbosacral area and plantar surface of foot having rectangular wave, 100µs pulse width, 150Hz frequency and 20mA intensity. TENS will be used on both sites at the same time. The 19 diode cluster head of the Laser 755 model will be used which have a wavelength of 640 nm (visible) and 950 nm (infrared) and a power of 10 mW (visible) and 15 mW (infrared) respectively. The cluster head will have 9 visible laser diodes and 10 infrared diodes. This session will be given for 4 days a week, for 4 consecutive weeks.

Category

Treatment - Devices

2

Description

Control group: The patients in this group will also receive the same treatment including TENS and LLLT but the laser unit will be switched off this time to get sham therapy. As the patient will be in prone lying with face turned downward and will be wearing protective goggles, so the participant will not be able to determine if the laser is turned off. 20-25 minutes of therapy session will be given in again in controlled group for 4 days a week, for 4 consecutive weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Physical therapy Department of University Physical Therapy and Rehabilitation Clinic, University of

Full name of responsible person

Asim Arif

Street address

1-Km Defence Road, near Bhuptian Chowk,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Lahore Teaching Hospital

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

The University of Lahore Teaching Hospital

Proportion provided by this source

100

Public or private sector

Private

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

The University of Lahore

Full name of responsible person

Shahzaib Anwer

Position

Research Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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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