

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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  $\geq 6$  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

##### Phone

+92 42 35405234

##### Email address

msptn02191037@student.uol.edu.pk

##### 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  $\geq 6$  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,

##### City

Lahore

##### Postal code

54000

##### Phone

+92 42 111 865 865

##### Email

info@uol.edu.pk

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

The University of Lahore Teaching Hospital

##### Full name of responsible person

Asim Arif

##### Street address

1-Km Defence Road, near Bhuptian Chowk,

##### City

Lahore

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54000

##### Phone

+92 42 111 865 865

##### Email

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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

##### Street address

4-B, Sadaat Street, Wahdat Colony,

##### City

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##### Province

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##### Email

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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**Postal code**

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**Email**

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## Person responsible for updating data

### 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**

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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