# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

29 Jun 2026

## Role of low level laser therapy on pain intensity and quality of life in patients with diabetic neuropathy

## Protocol summary

**Study aim**
Considering the importance of treating painful neuropathy in diabetic patients and the prevalence of this disease, it is necessary to find different therapies. The aim of this study was to investigate the effect of low-power laser on the improvement of pain and quality of life in these patients in order to be able to The effectiveness of this modality has been used to treat this disease

**Design**
In this Clinical trial, we investigated on 26 patients with De Quervain tenosynovitis who are eligible to treat, the intervention group was under treatment with extracorporeal shock wave (1000 impulse, 2 bar, and 15Hz) and placebo was under treatment without shock wave. The assessments tools were DISABILITIES OF THE ARM, SHOULDER, AND HAND (DASH) questionnaire, visual analog scale (VAS) and grip strength and used before and after treatment.

**Settings and conduct**
this is a double blind study which will be conducted in Isfahan, universities clinics in this city.

**Participants/Inclusion and exclusion criteria**
Patients with painful peripheral neuropathy older than 18 years of age Consent to participate in this study.

**Intervention groups**
Patients treated with 8 sessions of low-power laser as 1 session Placed per week) with a dose of 8 Jules per square centimeter on the back and foot of the foot, as well as in the popliteal area and on the head Fibula bone (and in the control group of the laser), a silent device that does not produce effective doses (for 8 sessions in the areas.

**Main outcome variables**
improvement of the sign and symptoms of the patients.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20190618043931N1**
Registration date: **2020-01-20, 1398/10/30**
Registration timing: **retrospective**

Last update: **2020-01-20, 1398/10/30**
Update count: **0**

**Registration date**
2020-01-20, 1398/10/30

**Registrant information**

**Name**
Shila Haghighat

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2016-03-20, 1395/01/01

**Expected recruitment end date**
2019-03-20, 1397/12/29

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Role of low level laser therapy on pain intensity and quality of life in patients with diabetic neuropathy

**Public title**
Role of low level laser therapy on pain intensity and quality of life in patients with diabetic neuropathy
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients with painful peripheral neuropathy older than 18 years of age Willingness to participate in the research project (filling the consent letter)
**Exclusion criteria:**
malignancy Active or untreated thyroid disease Infection with other known neurological and masculo-skeletal disorders simultaneously in the lower extremity
**Age**
From **18 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**
Target sample size: **40**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
40 patients with diabetic polyneuropathy (DNP) for 4 weeks would be enrolled in this double-blind randomized clinical trial. Patients will be randomized to receive placebo (sham laser) treatment (n = 20) or low level energy laser (n = 20). For randomization every patient will be pointed by a cod and after that every cod will be selected by provided randomization table. The score of VAS and SF36 will be evaluated in all of the patients in both groups immediately after, 2 and 4 weeks later.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
In this study the physician who evaluate the VAS criteria and SF36 forms of the patients (out put) will not know anything about the therapeutic method which is used for any patients. The method of therapy is also blind for patient.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Isfahan University of Medical Sciences
**Street address**
Hezar Jerib street,
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174673461
**Approval date**
2017-05-22, 1396/03/01
**Ethics committee reference number**
1396.3.036

## Health conditions studied

### 1

**Description of health condition studied**
Painful diabetic neuropathy: Painful diabetic neuropathy (PDN) is a common and debilitating complication of both types of diabetes mellitus. With this disorder the patients' sleep, mood, function and mainly quality of life (QOL) will be disturbed.
**ICD-10 code**
E08.40
**ICD-10 code description**
Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified

## Primary outcomes

### 1

**Description**
Pain and quality of life in patients with diabetic neuropathy
**Timepoint**
Before the intervention, immediately, 1 week and 1 week after the end of treatment in each group
**Method of measurement**
Pain intensity using VAS criteria and quality of life using SF36 questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: These patients will receive 8 sessions of low power laser. Treatments were administered twice weekly for 4 weeks.
**Category**
Rehabilitation

**2**

**Description**
Control group: These patients will recive 8 sessions of sham (non effectivee) laser. Treatments were administered twice weekly for 4 weeks.
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Clinics of Physical medicine affiliated with the Isfahan medical sciences universities.
**Full name of responsible person**
Najmeh Zare Zardini
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## Sponsors / Funding sources

**1**

**Sponsor**
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Esfahan University of Medical Sciences
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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**
Esfahan 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**
Esfahan University of Medical Sciences
**Full name of responsible person**
Najmeh Zare Zardini
**Position**
Consultant
**Latest degree**
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
Yes - There is a plan to make this available
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
Yes - There is a plan to make this available
**Data Dictionary**
Yes - There is a plan to make this available
**Title and more details about the data/document**
A portion of the information, such as information on the main outcome or the like, can be shared.
**When the data will become available and for how long**
Starting the access period 6 months after printing results
**To whom data/document is available**
Researchers working in academic institutions
**Under which criteria data/document could be used**
No specific conditions.
**From where data/document is obtainable**
Contact the author and researcher
**What processes are involved for a request to access data/document**
By emailing or calling the author as soon as you respond to the data requestor, you can access the data
**Comments**