

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 Haghghat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3627 5139

Email address

shila_haghghat@med.mui.ac.ir

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 musculo-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

Isfahan

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 receive 8 sessions of sham (non effective) 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

Street address

Al-Zahra hospital, Shohadaye Sofeh ave.,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ziba Farajzadegan

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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

Medical doctor

Other areas of specialty/work

Physical Medicine

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Position

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

Medical doctor

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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