

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The long-term Effect of low level laser therapy on clinical symptoms and electrophysiologic parameters in patients with carpal tunnel syndrome

Protocol summary

Study aim

determine the long term effects of LLLT and wrist splint and only splint with false laser on the outcome of mild to moderate carpal tunnel syndrome (CTS).

Design

This randomized, double-blind, controlled trial was conducted on 64 hands with mild and moderate CTS from both genders that were randomly assigned to 32 populated groups.

Settings and conduct

This randomized, double-blind, controlled trial was conducted during 2014 in outpatient clinics of Isfahan University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: pain and numbness in the median nerve area ; positive clinical CTS tests ;The mild or moderate disease (carpal tunnel syndrome). Exclusion criteria: the patients with severe CTS ;those receiving analgesic or anti-inflammatory drugs; history of steroid injection for CTS; history of diabetes or peripheral neuropathy

Intervention groups

Intervention group: Low level laser therapy (LLLT) is performed for 10 sessions (three times a week) using a calibrated laser device. Each treatment session lasts 20 minutes, which takes place in a rectangular area at 10 points in the volar wrist zone within the carpal tunnel area. In the control group sham laser therapy is used at the same intervals.

Main outcome variables

Pain, Nerve conduction, Peak sensory latency, Distal motor latency

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120716010297N5**

Registration date: **2018-06-20, 1397/03/30**

Registration timing: **prospective**

Last update: **2018-06-20, 1397/03/30**

Update count: **0**

Registration date

2018-06-20, 1397/03/30

Registrant information

Name

Leili Allahbakhshian

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2635-08-27, 2014/06/05

Expected recruitment end date

2636-08-27, 2015/06/05

Actual recruitment start date

2635-08-27, 2014/06/05

Actual recruitment end date

2636-08-27, 2015/06/05

Trial completion date

empty

Scientific title

The long-term Effect of low level laser therapy on clinical symptoms and electrophysiologic parameters in patients with carpal tunnel syndrome

Public title

The long-term Effect of low level laser therapy on carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pain and numbness in the median nerve territory Positive Phalen's and Tinel test Mild or moderate involvement of median nerve at the wrist according to electrophysiological findings.

Exclusion criteria:

Severe CTS based on electrodiagnostic criteria Receiving continuous analgesic or anti-inflammatory drugs Patients with history of steroid injections into the carpal tunnel History of thyroid disease, diabetes or peripheral neuropathy

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **64**

Actual sample size reached: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

All the patients were randomly assigned to two intervention groups using a computer-based random digit generator based on the consecutive admission numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

All the clinical examinations and the electrophysiological studies were performed by a physician who was blinded toward the study groups. the patients were also blinded toward their study group.

Placebo

Not 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 Jarib Ave, Azadi Square.

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8174673461

Approval date

2014-04-25, 1393/02/05

Ethics committee reference number

394210

Health conditions studied

1

Description of health condition studied

Carpal tunnel syndrome

ICD-10 code

G56.0

ICD-10 code description

Carpal tunnel syndrome

Primary outcomes

1

Description

Pain

Timepoint

6 months after treatment

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Nerve conduction

Timepoint

6 months after treatment

Method of measurement

Functional severity score (FSS), Symptoms severity scores (SSS)

3

Description

Peak sensory latency

Timepoint

6 months after treatment

Method of measurement

Electromyography (EMG)

4

Description

Distal motor latency

Timepoint

6 months after treatment

Method of measurement

Electromyography (EMG)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group received LLLT through 10 20-minute sessions three times a week. LLLT was done using calibrated laser device model 620 with continuous wave of 880 nm and a pulse wave of 905 nm with a maximum power of 1100 mV and frequency of 1000 Hz.

Category

Rehabilitation

2

Description

Control group: Patients in this group received sham laser therapy through the same instruction with the sham laser therapy. In addition, they received vitamin B1 at a dose of 300 mg per day and static night splinting for wrist for two months.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Kashani Hospital

Full name of responsible person

Shila Haghighat

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Ayatollah Kashani Hospital, Kashani St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ahmad Movahedian Attar

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Grant name

nil

Grant code / Reference number

31832

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

Zohre Zabihi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

Contact

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Professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

No - There is not 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

No - There is not 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

We have plan to publish the manuscript

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

What processes are involved for a request to access data/document

-

Comments