Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 tunel syndrom (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

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Leili Allahbakhshian

Name of organization / entity
Isfahan University of Medical Sciences

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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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Isfahan

Province
Isfehan

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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
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Sponsors / Funding sources

1

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Full name of responsible person
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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
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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