

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

###### Phone

+98 31 1668 7079

###### Email address

allahbakhshian@med.mui.ac.ir

##### 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.

## City

Isfahan

## Province

Isfahan

## Postal code

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

##### Street address

Ayatollah Kashani Hospital, Kashani St.

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##### Phone

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##### Email

sh-haghighat@med.mui.ac.ir

##### Web page address

<http://kashani.mui.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Ahmad Movahedian Attar

#### Street address

Hezar Jarib St. Azadi Sq.

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#### Postal code

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#### Phone

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#### Email

research@mui.ac.ir

#### Web page address

<http://www.research.mui.ac.ir>

#### 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

**Name of organization / entity**

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Saeed Khosrawi

**Position**

Professor

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Specialist

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## Person responsible for updating data

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

Physical Medicine

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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**