

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of the low-power laser combined with ultrasound in the treatment of carpal tunnel syndrome

Protocol summary

Study aim

Determination of effect of the low-power laser combined with ultrasound in the treatment of carpal tunnel syndrome

Design

Randomized controlled, single-blinded, and parallel-group design study

Settings and conduct

Patients with CTS will randomize into three groups (laser, ultrasound and laser with ultrasound). All patients will receive a wrist orthosis. one group undergo laser therapy (with wavelength of 830 nm and at a dose of 9 J/cm² on two points of 2 cm²), the second group undergo ultrasound therapy (15 minutes per session to the area over the carpal tunnel at a frequency of 1 MHz and an intensity of 1.0 W/cm², with pulsed mode duty cycle of 1:4) and the third group undergo laser with ultrasound therapy.

Participants/Inclusion and exclusion criteria

Patients with carpal tunnel syndrome Phalen test positive
Tonel test positive Prolonged nerve conduction velocity

Intervention groups

Laser therapy, low-power diode laser, with wavelength of 830 nm and at a dose of 9 J/cm² on two points of 2 cm² over the transverse ligament for two weeks as 5 sessions per week. Ultrasound treatment, 15 minutes per session to the area over the carpal tunnel at a frequency of 1 MHz and an intensity of 1.0 W/cm², with pulsed mode duty cycle of 1:4 and a transducer area of 5 cm² for two weeks as 5 sessions per week. Laser with ultrasound therapy, Laser (similar to the Lasre group) follow by ultrasound (similar to the ultrasound group) for for two weeks as 5 sessions per week.

Main outcome variables

Visual Analog Scale, distal sensory and motor latencies of the median nerve

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190202042581N1**

Registration date: **2019-02-14, 1397/11/25**

Registration timing: **prospective**

Last update: **2019-02-14, 1397/11/25**

Update count: **0**

Registration date

2019-02-14, 1397/11/25

Registrant information

Name

Mohammad Reza Asadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the low-power laser combined with ultrasound in the treatment of carpal tunnel syndrome

Public title

The effect of the low-power laser combined with ultrasound in the treatment of carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients diagnosed with mild to moderate carpal tunnel syndrome. The grades of the CTS were scrutinized using electrodiagnostic findings as the grades 0-3 were mild to moderate and grades 4-6 were identified as severe. Phalen and Tinel test positive.

Exclusion criteria:

cervical radiculopathy
Thoracic outlet syndrome
Peripheral neuropathy

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: 45

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible participants were randomly randomly divided, using the table of random numbers, into three groups of trials including: Groups of US, Laser and laser with US. Concealment of allocation was performed using sequentially numbered, sealed, opaque, stapled envelopes. The randomization was performed by primary investigator.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patients were blinded to the treatment allocation.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Hamedan University of Medical Sciences

Street address

Hamedan University of Medical Sciences, Fahmideh Blvd

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Hamadan

Postal code

6517838736

Approval date

2019-01-26, 1397/11/06

Ethics committee reference number

IR.UMSHA.REC.1397.790

Health conditions studied**1****Description of health condition studied**

Carpal tunnel syndrome

ICD-10 code

S64.1

ICD-10 code description

Injury of median nerve at wrist and hand level

Primary outcomes**1****Description**

pain severity

Timepoint

First session (before intervention), 10 and 21 day (after intervention)

Method of measurement

Visual Analogue Scale

2**Description**

Distal motor latency of median nerve

Timepoint

First session and last session

Method of measurement

Electrodiagnostic set up

3**Description**

Distal sensory latency of median nerve

Timepoint

First session and last session

Method of measurement

Electrodiagnostic set up

Secondary outcomes**1****Description**

Hand grip strength

Timepoint

First session and last session
Method of measurement
Dynamometer

2

Description
Pinch strength
Timepoint
First session and last session
Method of measurement
Dynamometer

Intervention groups

1

Description
First Intervention group: laser therapy: low-power diode laser, with wavelength of 830 nm and at a dose of 9 J/cm² on two points of 2 cm² over median nerve, in wrist area, for two weeks (10 session) as 5 sessions per week.
Category
Rehabilitation

2

Description
Second Intervention group: ultrasound therapy: Ultrasound treatment including: 15 minutes per session to the area over the carpal tunnel at a frequency of 1 MHz and an intensity of 1.2 W/cm², with pulsed mode duty cycle of 1:4 and a transducer area of 5 cm² for two weeks (10 sessions) as 5 sessions per week.
Category
Rehabilitation

3

Description
Third Intervention group: laser therapy with ultrasound therapy: Laser therapy (similar to the Lasre group) follow by ultrasound therapy (similar to the ulttrasound group) for two weeks (10 session) as 5 sessions per week.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Mobasher clinic
Full name of responsible person
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Sponsors / Funding sources

1

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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
Hamedan 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
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Position
Assistant professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable