

# 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/cm<sup>2</sup> on two points of 2 cm<sup>2</sup>), 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/cm<sup>2</sup>, 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/cm<sup>2</sup> on two points of 2 cm<sup>2</sup> 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/cm<sup>2</sup>, with pulsed mode duty cycle of 1:4 and a transducer area of 5 cm<sup>2</sup> 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)

##### Phone

+98 81 3423 0949

##### Email address

m.asadi@umsha.ac.ir

##### 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

#### City

Hamedan

#### Province

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/cm<sup>2</sup> on two points of 2 cm<sup>2</sup> 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/cm<sup>2</sup>, with pulsed mode duty cycle of 1:4 and a transducer area of 5 cm<sup>2</sup> 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**

Mohammad Reza Asadi

#### **Street address**

Mahdieh Blvd

#### **City**

Hamedan

#### **Province**

Hamadan

### **Postal code**

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### **Phone**

+98 81 3832 7512

### **Email**

reza.asadi21@yahoo.com

## **Sponsors / Funding sources**

### 1

### **Sponsor**

#### **Name of organization / entity**

Hamedan University of Medical Sciences

#### **Full name of responsible person**

Saeed Bashirian

#### **Street address**

Fahmideh Blvd

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#### **Province**

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#### **Postal code**

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#### **Phone**

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#### **Email**

S\_bashirian@yahoo.com

### **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**

Hamedan University of Medical Sciences

#### **Full name of responsible person**

Mohammad Reza Asadi

#### **Position**

Assistant professor

#### **Latest degree**

Ph.D.

#### **Other areas of specialty/work**

Physiotherapy

#### **Street address**

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## Person responsible for scientific inquiries

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Ph.D.

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## Person responsible for updating data

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Hamedan University of Medical Sciences

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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