

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative evaluation of high intensity laser & extracorporeal shockwave therapy on pain , symptoms & electrodiagnostic parameters of patients with carpal tunnel syndrome

#### Protocol summary

##### Study aim

Determining the difference in the effect of high power laser treatment and extracorporeal shock waves on pain, symptoms and electrodiagnostic parameters of patients with carpal tunnel syndrome.

##### Design

It is a double-blind randomized clinical trial. The sampling method is easy. Random division with Random Allocation Sampling method: available and patients with the desired criteria Randomization method: random sequence using [www.randomization.com](http://www.randomization.com)

##### Settings and conduct

outpatient clinics of Medical Sciences teaching hospitals After randomization, they are assigned to one of the two HILT and ESWT groups. All patients are advised to modify their lifestyle and use a wrist splint at night and use B1 300 mg tablets daily for one month. Patients were followed up in person before the intervention, the fourth week and the twelfth week.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with mild and moderate idiopathic CTS Age over 18 years and under 60 years Non-entry criteria: 1-Severe cases (absence of sensory or motor wave in the nerve strip test) 2-Cervical radiculopathy and 3-peripheral polyneuropathy such as diabetes and... 4-Active hand infection during visit 5-Finding a fixable underlying cause for CTS 6-Pregnancy 7-An underlying disease such as rheumatoid arthritis 8-Receiving painkillers and painkillers in the past 9-Injection test for treatment of CTS during the last 3 months 10-Presence of coagulation disorder 11-Using a heart pacemaker 12-Untreated or treated cancer

##### Intervention groups

intervention groups: One group is subjected to high power laser and one group is subjected to shockwave treatment. Also, B1 300 drug and wrist band are prescribed for both groups.

##### Main outcome variables

visual analog scale [VAS], Boston questionnaire, distal sensory latency parameters - Across canal Sensory conduction velocity and distal motoric latency in EMG-NCV.

#### General information

##### Reason for update

##### Acronym

CTS/HILT/ESWT

##### IRCT registration information

IRCT registration number: **IRCT20240317061317N1**

Registration date: **2024-04-18, 1403/01/30**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-04-18, 1403/01/30**

Update count: **0**

##### Registration date

2024-04-18, 1403/01/30

##### Registrant information

##### Name

mahdi Dastanpoor hossein abadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3452 7933

##### Email address

mahdi.dastanpoor70@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-04-03, 1403/01/15

##### Expected recruitment end date

2024-09-05, 1403/06/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparative evaluation of high intensity laser & extracorporeal shockwave therapy on pain , symptoms & electrodiagnostic parameters of patients with carpal tunnel syndrome

**Public title**

Investigating the therapeutic effect of laser and shockwave on carpal tunnel syndrome or wrist nerve adhesions

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients with mild and moderate idiopathic CTS Age above 18 years and less than 60 years Absence of severe cases (absence of sensory or motor wave in the nerve strip test) Absence of underlying disease such as rheumatoid arthritis Absence of cervical radiculopathy and peripheral polyneuropathy such as diabetes and...

**Exclusion criteria:**

Active hand infection during visit History of injection to treat CTS during the last 3 months Using a heart pacemaker pregnancy Untreated or treated cancer Receiving painkillers and painkillers during the past period

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A simple randomization method is used, and sampling will be done by the method of alternating blocks of 2 pieces. In this way, 10 blocks of 3 pieces and each block contains 3 letters from the letters A and B, including AAB-ABA-BBA-BAB-... will have. (two groups of 30) each patient is given a card randomly. The cards are in sealed envelopes and the technician takes the envelopes and hands them to the patients.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The method of blinding is double-blind, only the first doctor who is responsible for the intervention knows the type of intervention. In order to blind the patient, one main intervention and one other group intervention are performed with the device turned off. Other people involved in the study, including the second doctor who is responsible for conducting the electrodiagnostic test (EMG-NCV), the person responsible for the follow-up of the patients, and the person responsible for analyzing the data are unaware of the placement of the patients in group A or B.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

کمیته اخلاق در پژوهش دانشگاه علوم پزشکی اصفهان

**Street address**

Hazar Jarib St., Isfahan University of Medical Sciences and Health Care Services, Building No. 4, Research and Technology Vice-Chancellor

**City**

esfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2024-03-14, 1402/12/24

**Ethics committee reference number**

IR.MUI.MED.REC.1402.473

**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**

The scale of two methods of laser and shock wave therapy on patient's pain

### **Timepoint**

Before the start of the intervention - 4 and 12 weeks after the intervention.

### **Method of measurement**

visual analogue scale

## **2**

### **Description**

Comparison of two methods of laser and shock wave therapy on motor and sensory latency of the distal.

### **Timepoint**

Before the start of the intervention - 12 weeks after the intervention.

### **Method of measurement**

EMG-NCV

## **Secondary outcomes**

## **1**

### **Description**

Comparison of laser therapy and shock wave therapy on the severity of symptoms and functional status of carpal tunnel syndrome

### **Timepoint**

Before the intervention - 4 and 12 weeks after the intervention

### **Method of measurement**

Boston questionnaire

## **Intervention groups**

## **1**

### **Description**

Intervention group: the group including taking B1 300 drug for one month and wristband for 3 months and performing laser therapy with HILT low fluence protocol (1.6 W- 8 J/cm<sup>2</sup>) BTL-6000 device, with a combination of wavelength 808 & 1064 nm for 36 seconds and 5 sessions in 2 weeks.

### **Category**

Treatment - Devices

## **2**

### **Description**

Intervention group: the group including the use of B1 300 drug for one month and wristband for 3 months and performing ESWT shock wave therapy using the radial method and 1000 shock protocol of 0.05 mJ/mm<sup>2</sup> and with a frequency of 5 Hz, for this group in three sessions in two week (at least one session per week).

### **Category**

Treatment - Devices

## **Recruitment centers**

## **1**

### **Recruitment center**

### **Name of recruitment center**

Physical Medicine Clinic of Isfahan University of Medical Sciences Hospitals

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

mahdi dastanpoor hossein abadi

### **Street address**

Kaveh St., Golestan St., Hesa St., Ostad Shahryar Alley, 5 Shagaig dead end, plate 57

### **City**

esfahan

### **Province**

Isfahan

### **Postal code**

8196991951

### **Phone**

+98 31 3452 7933

### **Email**

shadowdidas@gmail.com

## **Sponsors / Funding sources**

## **1**

### **Sponsor**

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

Esfahan University of Medical Sciences

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

Beheshte Toghiani

#### **Street address**

Hazar Jarib St., Isfahan University of Medical Sciences and Health Care Services, Faculty of Medicine

#### **City**

esfahan

#### **Province**

Isfahan

#### **Postal code**

8174673461

#### **Phone**

+98 31 3792 8092

#### **Email**

dean@med.mui.ac.ir

### **Grant name**

### **Grant code / Reference number**

### **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**

20

### **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**

Hamed zare dehnavi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

Hasht Behesht East St., Ahad Alley, Hadith dead end

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8157957764

**Phone**

+98 25 3750 4171

**Fax****Email**

hamdzar29@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

babak vahdat pour

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

**Street address**

Isfahan University of Medical Sciences, Isfahan, Iran

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3792 9131

**Fax****Email**

vahdatpour@med.mui.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mahdi Dastanpoor hossein abadi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

Kaveh St., Golestan St., Hesa St., Hajj Square, Ostad  
Shahryar St., Shagaig dead end, 5, plate 57

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8196991951

**Phone**

+98 31 3452 7933

**Fax****Email**

mahdi.dastanpoor70@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

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**

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**

Undecided - It is not yet known if there will be a plan to make this available