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

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)

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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

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

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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/cm2) 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/mm2 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
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Sponsors / Funding sources

1

Sponsor
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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
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

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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