Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparative Evaluation of High-power Laser versus Anti-Inflammatory Effects of Corticosteroid Injection on Symptoms and Function in Patients with Mild to Moderate Carpal Tunnel Syndrome

Protocol summary

Study aim
Comparison of the effectiveness of high-power laser versus corticosteroid injection in improving the function and symptoms of patients with mild and moderate carpal tunnel syndrome

Design
The study is a randomized, controlled, parallel-group, single-blind trial involving 40 patients. Block randomization with blocks of four was used, and Excel software was employed for randomization.

Settings and conduct
Patients with mild and moderate carpal tunnel syndrome who visit the physical medicine clinics of Imam Khomeini and Sina hospitals during the study period and meet the inclusion criteria will be enrolled in the study. They will be randomly assigned to either the intervention or control group using block randomization method with block size of 4. This study will be conducted in a single - blind manner, such that physicians, and data analysts will be unaware of the type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Age > 18, Mild to moderate CTS (based on nerve conduction study) Exclusion Criteria: Surgical indication, Neurological disorders, pregnancy, infection, malignancy, Allergy or contraindication to corticosteroids, Prior CTS surgery or corticosteroid injection in the last 6 months

Intervention groups
Intervention: Six sessions of high-power laser therapy were applied to the flexor retinaculum of the affected wrist. The patient sat comfortably with the forearm on the table. Both patient and physician wore protective goggles. The scanner probe was moved back and forth over the area for five minutes. Treatment followed a specific carpal tunnel protocol (30 Hz, 1.5 W, 30 J/cm^2), conducted over three weeks, every other day. Control: Standard treatment with a 1 ml injection of 40 mg triamcinolone at the distal wrist crease

Main outcome variables
Boston Questionnaire Score, Pain and Numbness Severity, Patient Satisfaction, Median Nerve Conduction Study (NCS) Findings

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241228064194N1**
Registration date: **2025-04-20, 1404/01/31**
Registration timing: **prospective**

Last update: **2025-04-20, 1404/01/31**
Update count: **0**

Registration date
2025-04-20, 1404/01/31

Registrant information

Name
Fateme Khosravipour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 936 038 5602

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-05-05, 1404/02/15

Expected recruitment end date
2025-06-05, 1404/03/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative Evaluation of High-power Laser versus Anti-Inflammatory Effects of Corticosteroid Injection on Symptoms and Function in Patients with Mild to Moderate Carpal Tunnel Syndrome

Public title
High power Laser in carpal tunnel syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years mild to moderate carpal tunnel syndrome (CTS) based on nerve conduction study (NCS) findings
Exclusion criteria:
Patients who have surgical indications, such as severe weakness, thenar muscle atrophy, or lack of response to treatment. Concurrent neurological disorders based on electromyography observations, such as polyneuropathy, ulnar neuropathy, proximal median neuropathy, plexopathy, mononeuritis multiplex, cervical radiculopathy. pregnancy infection malignancy patients who have received corticosteroid injections in the past six months. patients with a history of wrist surgery for CTS treatment, allergy to corticosteroids contraindications for corticosteroids
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
randomized (block randomization method with the block size 4 using Excel software), phase 4 on 40 patients
Blinding (investigator's opinion)
Single blinded
Blinding description
This was a single-blind study. A physician (specialist in physical medicine and rehabilitation), who was unaware of the treatment group of each patient, was responsible for the initial electrodiagnostic assessment and for collecting data from all patients (including demographic data, pain intensity [VAS], Boston questionnaire, grip strength, and electrodiagnostic findings). Another physician performed high-power laser therapy, and a therapist administered the cortisone injections, both of whom were blinded to the patients' group assignments. The patients themselves were not blinded to the treatment they received.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Emam Khomeini complex Hospital
Street address
No.5.Gharib St,Keshavarz Blvd., Tehran, Iran
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Tehran
Postal code
1419733141
Approval date
2023-08-29, 1402/06/07
Ethics committee reference number
IR.TUMS.IKHC.REC.1402.210

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
Boston Questionnaire Score
Timepoint
Before the intervention, 2 weeks, 1 month, and 3 months after the completion of the intervention.
Method of measurement
Boston Questionnaire

2

Description
Patient Satisfaction level
Timepoint
Before the intervention, 2 weeks, 1 month, and 3 months after the completion of the intervention.
Method of measurement
Patient Satisfaction Questionnaire

3

Description
Visual Analog Scale for pain and numbness score
Timepoint
Before the intervention, 2 weeks, 1 month, and 3 months after the completion of the intervention.
Method of measurement
Visual Analog Scale for pain and numbness

4

Description
Median Nerve Conduction Study (NCS) Findings
Timepoint
Before the intervention and 3 months after the completion of the intervention.
Method of measurement
Nerve Conduction Study (NCS) device.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients will receive six sessions of high-power laser therapy over three weeks, with a two-day interval between each session, each lasting five minutes, according to the predefined protocol on the Novin high-power laser device (30 Hz frequency, 1.5 W power, and 30 J/cm² dose). The device is calibrated before use and is the same for all patients. Due to the lack of consistency in laser parameters across studies using high-power lasers, we used the preset program for carpal tunnel syndrome (CTS) provided by the device. The session begins with the patient seated in a relaxed position, with the forearm resting on the treatment table. In the main unit of the device, the therapist selects the CTS treatment program. Then, after providing protective glasses for both the patient and therapist, the treatment begins, and the scanner probe is moved back and forth over the flexor retinaculum of the wrist (3 cm proximal and distal to the wrist crease) for five minutes, simultaneously with pedal pressure, which activates the laser. The pedal pressure corresponds to the laser exposure. All these steps are performed by one physician for all patients.
Category
Treatment - Devices

2

Description
Control group: For this group of patients, routine and standard treatment for carpal tunnel syndrome is performed. This treatment includes an injection of 1 mL of triamcinolone (40 mg) in the distal wrist crease.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Khomeini complex hospital
Full name of responsible person
Dr Fateme Khosravipour
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Number 21, Gharib St. Keshavarz Blvd, Vali-e Asr Ave., Tehran , Iran
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2

Recruitment center
Name of recruitment center
Sina hospital
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Tehran 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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Full name of responsible person
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Position
physical medicine and rehabilitation resident

Latest degree
Medical doctor

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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
"There is no more information available."
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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available