Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 2026

Evaluation of the comparative effect of high-power and low-power laser and drug therapy in improving the symptoms, function and sonographic findings in patients with mild to moderate carpal tunnel syndrome

Protocol summary

Study aim
Determining and comparing the effect of high-power and low-power laser and drug therapy in improving the symptoms, function, and sonographic findings in patients with carpal tunnel syndrome

Design
A randomized, double-blind clinical trial with the parallel groups; on 66 patients. Randomization by lottery

Settings and conduct
In this randomized double-blind clinical trial study, 66 eligible patients referred to Amin Hospital in Isfahan will be included in the study and randomly divided into three groups. For patients in the first group, splints, gabapentin, and vitamin B1, in the second and third groups, in addition to the mentioned treatment, low-power laser and high-power laser are performed, respectively. The intervention will be performed in such a way that the patient and the investigator, outcome assessor, and data analyzer will have no knowledge of the type of intervention. Then the symptoms, function and sonographic findings will be compared between the three groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria include patients with mild to moderate degrees of carpal tunnel syndrome in the age group over 18 years and no history of carpal tunnel injection in a recent month and consent to participate in the study. Exclusion criteria include having neuropathic diseases, having systemic diseases that affect treatment, having a history of carpal tunnel surgery, and pregnancy.

Intervention groups
Control group: For patients in this group, splints, gabapentin, and vitamin B1 are prescribed. Intervention group 1: In this group, in addition to splint administration, gabapentin, and vitamin B1, patients undergo low-power laser. Second intervention group: In this group, in addition to prescribing splints, gabapentin, and vitamin B1, patients undergo high-power laser.

Main outcome variables
Symptoms; Functional status; Pain; Nerve and muscle strip findings; Ultrasound findings

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220423054620N1**
Registration date: **2022-06-08, 1401/03/18**
Registration timing: **prospective**

Last update: **2022-06-08, 1401/03/18**
Update count: **0**

Registration date
2022-06-08, 1401/03/18

Registrant information

Name
parisa monzavi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-22, 1401/04/01

Expected recruitment end date
2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the comparative effect of high-power and low-power laser and drug therapy in improving the symptoms, function and sonographic findings in patients with mild to moderate carpal tunnel syndrome

Public title

Comparison of the effect of high-power and low-power laser and drug therapy in improving the symptoms, function and sonographic findings in patients with carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with mild to moderate carpal tunnel syndrome Age category over 18 years No history of injection in the carpal tunnel in a recent month Consent to participate in the study

Exclusion criteria:

Having neuropathic diseases Having systemic diseases that affect treatment (such as hypothyroidism, diabetes, rheumatism) Having a history of carpal tunnel surgery Pregnancy

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 66 eligible patients are randomly selected. For this, the letter A is written on 22 sheets, the letter B is written on 22 sheets, and the letter C is written on 22sheets, and each of them is placed in an envelope. Each patient is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of three groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, all three groups will be prescribed drug treatment, and in addition, two groups will be under low-power or high-power laser. Due to the difference in the laser power intensity, the Care provider is aware of the type of intervention in each group, but the patient will not be aware of the laser power used. In addition, the investigator, outcome assessor, and data analyzer will not know the type of intervention in the three groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfehan

Postal code

8179964167

Approval date

2022-02-13, 1400/11/24

Ethics committee reference number

IR.MUI.MED.REC.1400.803

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

Symptoms

Timepoint

Before treatment, one month and three months after treatment

Method of measurement

Boston Questionnaire

2

Description

Functional status

Timepoint
Before treatment, one month and three months after treatment
Method of measurement
Boston Questionnaire

3

Description
Pain
Timepoint
Before treatment, one month and three months after treatment
Method of measurement
Visual Analog Scale (VAS)

4

Description
Nerve Conduction Velocity (NCV) across wrist
Timepoint
Before treatment and three months after treatment
Method of measurement
Nerve and muscle strip

5

Description
Sensory nerve action potential (SNAP) across wrist
Timepoint
Before treatment and three months after treatment
Method of measurement
Nerve and muscle strip

6

Description
Compound Muscle Action Potential (CMAP) across wrist
Timepoint
Before treatment and three months after treatment
Method of measurement
Nerve and muscle strip

7

Description
Cross-sectional area (CSA) carpal tunnel
Timepoint
Before treatment and three months after treatment
Method of measurement
Sonography

Secondary outcomes

empty

Intervention groups

1

Description
Control group: In this group, patients have routinely prescribed wrist splints, in addition to vitamin B1 and gabapentin 100 mg for two weeks.
Category
Treatment - Drugs

2

Description
Intervention group 1: In this group, patients are prescribed routine treatment including a wrist splint, vitamin B1, and gabapentin 100 mg for two weeks. In addition, patients are treated with a low-power laser (New Vision device) five days a week (for two weeks) with a wavelength of 808 nm and a frequency of 1000 Hz, and an energy of 4 J/cm2 five days a week (for two weeks). The device is placed on the pulse settings and in the area of the carpal tunnel and the palm area in the path of the median nerve branches, the median nerve of fingers 1, 2, 3, and 4 will be fast manual scanning.
Category
Treatment - Devices

3

Description
Intervention group 2: In this group, patients are prescribed routine treatment including wrist splint, vitamin B1 and gabapentin 100 mg for two weeks. In addition, patients are treated with a high-power laser (Fisioline device) five days a week (for two weeks) with a wavelength of 1064-910 nm and a frequency of 1000 Hz and an energy of 4 J/cm2. The device is placed on the pulse settings and in the area of the carpal tunnel and the palm area in the path of the median nerve branches, the median nerve of fingers 1, 2, 3 and 4 will be fast manual scanning.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Amin Hospital
Full name of responsible person
Raziye Maghroori
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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?
No
Title of funding source
Isfahan 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

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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 further 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available