

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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)

Phone

+98 31 3778 8275

Email address

parisamonzavi@resident.mui.ac.ir

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 22 sheets, 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
Isfahan
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

Street address

Ibn Sina Street

City

Isfahan

Province

Isfahan

Postal code

5314181486

Phone

+98 31 3445 5051

Email

maghroori@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash Dastjerdi

Street address

Vice Chancellor for Research, School of Medicine,
Hezar Jarib Street, Isfahan.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8597

Email

dean@med.mui.ac.ir

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

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Raziye Maghroori

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Physical Medicine and Rehabilitation Department,
Kashani Hospital, Kashani Street.

City

Isfahan

Province

Isfahan

Postal code

8183983434

Phone

+98 31 3233 0091

Email

maghroori@mui.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Raziye Maghroori

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Physical Medicine and Rehabilitation Department,
Kashani Hospital, Kashani Street.

City

Isfahan

Province

Isfahan

Postal code

8183983434

Phone

+98 31 3233 0091

Email

maghroori@mui.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Parisa Monzavi

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Physical Medicine and Rehabilitation Department,
Kashani Hospital, Kashani Street.

City

Isfahan

Province

Isfahan

Postal code

8183983434

Phone

+98 31 3233 0091

Email

parisamonzavi@resident.mui.ac.ir

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