

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Clinical Outcomes of Low Versus Versus High Intensity Laser Therapy in the Treatment of Patients with Subacute Carpal Tunnel Syndrome

Protocol summary

Study aim

To Assess Clinical outcomes of low versus high intensity laser therapy in the treatment of patients with subacute carpal tunnel syndrome.

Design

Three arm parallel group randomised trial with blinded participants and Assessors

Settings and conduct

At the Physical Therapy Department, Central Park Medical College, Lahore, Pakistan

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Participants with mild CTS confirmed by EMG-NCV Exclusion Criteria: Severe CTS (e.g., missing sensory/motor waves) or mild CTS (sensory latency >3.5 ms at the third digit). Recent therapy, exercise (within 2 weeks), or analgesic/anti-inflammatory use (within 1 week).

Intervention groups

Group A- High-intensity laser therapy + Physical Therapy
Group B -Low-intensity laser therapy group + Physical Therapy
Group C -Physical Therapy

Main outcome variables

visual analog scale, median compound muscle action potential (CMAP), and sensory nerve conduction studies

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241111063665N1**
Registration date: **2025-03-17, 1403/12/27**
Registration timing: **registered_while_recruiting**

Last update: **2025-03-17, 1403/12/27**

Update count: **0**

Registration date

2025-03-17, 1403/12/27

Registrant information

Name

Arif Ali Rana

Name of organization / entity

Central Park Medical College Lahore

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Pakistan

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Email address

arifalirana@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-29, 1403/06/08

Expected recruitment end date

2025-04-29, 1404/02/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Outcomes of Low Versus Versus High Intensity Laser Therapy in the Treatment of Patients with Subacute Carpal Tunnel Syndrome

Public title

Clinical Outcomes of Low Versus Versus High Intensity Laser Therapy in the Treatment of Patients with Subacute Carpal Tunnel Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of participants 20-40 years Individuals who have been diagnosed with carpal tunnel syndrome, regardless

of gender Based on electromyography-nerve conduction velocity (EMG-NCV) investigation, the diagnosis of mild carpal tunnel syndrome was confirmed. This involves the involvement of both sensory and motor fibers to the extent that none are absent, with a sensory and motor delay of more than 3.6 msec and 4.1 msec, respectively.

Exclusion criteria:
According to an EMG-NCV investigation, there are patients with mild (sensory nerve latency >3.5 ms at third digit) and severe (missing sensory or motor waves) CTS. Patients with a history of continuous physical therapy or exercise during the previous two weeks, or taking analgesic or anti-inflammatory drugs during the week before the baseline assessment. Hypothyroidism Cancer Active infection Pulmonary disease Acquired immunodeficiency syndrome Associated Myopathy Myelopathy History of neck and/or shoulder surgery, drug abuse, corticosteroid consumption, and high-risk pregnancy

Age
From **20 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **69**

Randomization (investigator's opinion)
Randomized

Randomization description
The study utilized block randomization to allocate participants into two groups. Individuals were the unit of randomization. To ensure balance between groups, blocks of size 4 or 6 were created, with a pre-determined sequence of assignments (e.g., AABB, ABBA). A computer-based randomization tool was used to generate the random sequence, ensuring unbiased group allocation. The sequence was concealed, meaning participants were assigned to the next available slot in the random sequence without prior knowledge of the upcoming assignments. This allocation concealment prevented bias in group assignment. However, since the sampling method was non-probability, generalizability may be limited. The randomization tool ensured that the process was reliable and transparent.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study used double blinding to reduce bias. Participants were unaware of their group assignments and the specifics of the treatment they received. Similarly, assessors evaluating the outcomes were also blinded to the group allocations. This ensured that neither the participants' responses nor the assessors' evaluations were influenced by knowledge of the treatment protocols. The double-blinding helped maintain the objectivity and integrity of the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee (REC-Phd) FAHS,
University of Lahore

Street address

6-km Defence Road Bhubatian Chawk Lahore

City

Lahore

Postal code

54600

Approval date

2024-08-22, 1403/06/01

Ethics committee reference number

REC-02#PhD /IM/2024

Health conditions studied

1

Description of health condition studied

Subacute Carpal Tunnel Syndrome

ICD-10 code

G56.0

ICD-10 code description

Carpal tunnel syndrome

Primary outcomes

1

Description

Ultrasound changes

Timepoint

Before intervention and after 5 weeks of Intervention

Method of measurement

Ultrasound

2

Description

CMAP and SNAP latencies

Timepoint

Before intervention and after 5 weeks of Intervention

Method of measurement

Nerve Conduction Studies

Secondary outcomes

1

Description

Pain

Timepoint

Before intervention and after 5 weeks of Intervention

Method of measurement

Visual Analogue Scale

2

Description

Electrophysiological Changes

Timepoint

Before intervention and after 5 weeks of Intervention

Method of measurement

Nerve Conduction Studies and EMG

3

Description

Hand Grip/ Strength

Timepoint

Before intervention and after 5 weeks of Intervention

Method of measurement

Handheld Dynamometer

4

Description

Quality of Life

Timepoint

Before intervention and after 5 weeks of Intervention

Method of measurement

Quality of Life Scale

5

Description

Hand Function

Timepoint

Before intervention and after 5 weeks of Intervention

Method of measurement

SF-36

Intervention groups

1

Description

Intervention group: A High-Intensity Laser Therapy + Physical Therapy Participants in Group A will receive High-Intensity Laser Therapy combined with Physical Therapy. The laser therapy will be delivered using a device emitting low fluency (1/6 W, 8 J/cm²). The therapy will be administered three times per week for 5 weeks. Alongside laser therapy, participants will perform four standard exercises: active and active-assisted wrist extension, active finger flexion and extension, and weight-bearing exercises on extended wrists. These treatments aim to assess the combined effects of high-

intensity laser therapy and physical therapy on pain reduction and functional recovery.

Category

Treatment - Devices

2

Description

Intervention group: B Low-intensity laser therapy group + Physical Therapy Group B will receive Low-Level Laser Therapy (LLLT) in combination with Physical Therapy. The LLLT will be delivered using high fluency (50 mW, 20 J/cm²), administered three times per week for 5 weeks. As with Group A, participants will perform the same four standard exercises, aimed at improving wrist and finger movements along with functional strength. This group will evaluate the impact of low-intensity laser therapy combined with physical therapy on recovery and pain management.

Category

Treatment - Devices

3

Description

Intervention group: C Physical Therapy Group C will receive Physical Therapy only, with no laser therapy. The same four standard exercises (active wrist extension, active finger flexion/extension, and weight-bearing wrist exercises) will be provided. This group serves as a control to compare the effectiveness of physical therapy alone against the laser therapy groups. Participants will receive no laser treatment, allowing for assessment of the placebo effect of the laser therapy

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Physical therapy- Central Park Medical College, Lahore, Pakistan

Full name of responsible person

Arif Ali Rana

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

self

Full name of responsible person

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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

Self

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

University of Lahore

Full name of responsible person

Arif Ali Rana

Position

associate Professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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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

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