Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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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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 Bhobatian 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
Dr. Arif Ali Rana
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665-F block Central Park Housing Society Ferozpur Road Lahore
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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
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Arif Ali Rana
Position
associate Professor
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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