

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The comparison of effectiveness of low-level laser and extracorporeal shockwave in patients with carpal tunnel syndrome

Protocol summary

Study aim

The comparison of effectiveness of routine treatment, low-level laser therapy, and Extracorporeal shockwave on pain, function, electrophysiologic and sonography parameters in patients with carpal tunnel syndrome

Design

Randomized, controlled, three arm, and superiority trial. Outcome assessor and the person who will perform statistical analysis are blinded.

Settings and conduct

Biomechanic laboratory of physiotherapy of Faculty of Rehabilitation of Tehran University of Medical Sciences.

Participants/Inclusion and exclusion criteria

The patients will be included in this study if they have carpal tunnel syndrome, and age between 20 and 60. Exclusion criteria are as follows: History of fracture and dislocation in wrist and hand complex during the last 3 months, history of surgery in wrist and hand complex during the last 6 months, having cervical radiculopathy and thoracic outlet syndrome, pregnancy, receiving coricosteriod injection and physiotherapy treatment during the last 3 months, neurological and systemic diseases, such as rheumatoid arthritis, Parkinson, Multiple Sclerosis

Intervention groups

Those patients who will meet the study inclusion criteria will be allocated randomly into 3 groups: Control group: The control group will receive routine treatments including mobilization, ultrasound, stretching techniques, hot pack, and TENS five sessions per week for two weeks. Low-level laser therapy group: This group will receive Low-level laser on carpal tunnel group five sessions per week for two weeks Extracorporeal shockwave group : This group will receive Extracorporeal shockwave two sessions per week for two weeks

Main outcome variables

Primary : Pain, function, grip and pinch power Secondary : median NCV, CSA of median nerve, amplitude of median sensory nerve, amplitude of median motor

nerve, latency of median sensory nerve, latency of median motor nerve,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220504054734N1**

Registration date: **2022-06-30, 1401/04/09**

Registration timing: **prospective**

Last update: **2022-06-30, 1401/04/09**

Update count: **0**

Registration date

2022-06-30, 1401/04/09

Registrant information

Name

Amir Hossein Ghasemi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-21, 1401/04/30

Expected recruitment end date

2022-10-07, 1401/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of effectiveness of low-level laser and extracorporeal shockwave in patients with carpal tunnel syndrome

Public title

Low-level laser and extracorporeal shockwave in patients with carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with carpal tunnel syndrome Age between 20 and 60

Exclusion criteria:

History of fracture and dislocation in wrist and hand complex during the last 3 months History of surgery in wrist and hand complex during the last 6 months Cervical radiculopathy and thoracic outlet syndrome Pregnancy Receiving corticosteroid injection and physiotherapy treatment during the last 3 months Neurological and systemic diseases, such as rheumatoid arthritis, Parkinson, Multiple Sclerosis

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **54**

More than 1 sample in each individual

Number of samples in each individual: **54**

54 (18 patients per group)

Randomization (investigator's opinion)

Randomized

Randomization description

Those patients who will meet the study inclusion criteria will be allocated randomly into 3 groups: the control group (routine conservative treatment group), low-level laser therapy group, and extracorporeal shockwave group . A block balanced randomization (1:1:1) with a block size of 6 will be used for random allocation. A random allocation will be performed using the website of www.randomization.com. To conceal the sequence of the random allocation, numbered closed envelopes containing A, B, C groups will be used. Group A will receive the routine conservative treatment, group B will receive low-level laser therapy, and Group C will receive extracorporeal shockwave.

Blinding (investigator's opinion)

Single blinded

Blinding description

In the present study, those who will assess the outcomes and will perform statistical analysis are blinded while the

therapist and participants are not blinded. To blind outcome assessor and the person who will perform statistical analysis : no information will be given about type of groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Biomedical Research Ethics Committee of School of Nursing and Midwifery & Rehabilitation of Tehran U

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Department of research and technology of Tehran University of Medical Sciences; Keshavarz Blvd; Ghods St

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Tehran

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Tehran

Postal code

3439123900

Approval date

2020-10-06, 1399/07/15

Ethics committee reference number

IR.TUMS.FNM.REC.1399.107

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**

Pain

Timepoint

At baseline, after two weeks(the end of the treatment), after a one-week follow-up period

Method of measurement

Visual analog scale

2

Description

function

Timepoint

At baseline, after two weeks(the end of the treatment),
after a one-week follow-up period

Method of measurement

Boston Carpal Tunnel Syndrome Questionnaire

3

Description

Grip power

Timepoint

At baseline, after two weeks(the end of the treatment),
after a one-week follow-up period

Method of measurement

Dynamometer

4

Description

Pinch power

Timepoint

At baseline, after two weeks(the end of the treatment),
after a one-week follow-up period

Method of measurement

Dynamometer

Secondary outcomes

1

Description

Amplitude of median sensory nerve

Timepoint

At baseline, after two weeks (the end of the treatment)

Method of measurement

Electromyography apparatus

2

Description

Amplitude of median motor nerve

Timepoint

At baseline, after two weeks (the end of the treatment)

Method of measurement

Electromyography apparatus

3

Description

Latency of median sensory nerve

Timepoint

At baseline, after two weeks (the end of the treatment)

Method of measurement

Electromyography apparatus

4

Description

Latency of median motor nerve

Timepoint

At baseline, after two weeks (the end of the treatment)

Method of measurement

Electromyography apparatus

5

Description

Median nerve conduction velocity

Timepoint

At baseline, after two weeks (the end of the treatment)

Method of measurement

Electromyography apparatus

6

Description

Cross sectional area of median nerve

Timepoint

At baseline, after two weeks (the end of the treatment)

Method of measurement

Sonography apparatus

Intervention groups

1

Description

Intervention group: This group will receive Low-level laser , five sessions per week, for two weeks.Each session will last for 5 minutes. Patients will be asked to lay in sitting position and the probe will be hold between the distal crease and kaplan- cardinal line

Category

Rehabilitation

2

Description

Intervention group: This group will receive extracorporeal shockwave two sessions per week, for two weeks. Each session will last for 3-5 minutes. Patients will be asked to lay in sitting position and the probe will be hold on the flexor reticulum of the wrist.

Category

Rehabilitation

3

Description

Control group: The control group will receive routine treatments including mobilization, ultrasound (1MHz, 1 W/cm2, for 5 minutes) stretching techniques, hot pack, and TENS (25 minutes) five sessions per week, for two weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Ali Hossein Ghasemi

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

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Full name of responsible person

Akbar Fotoohi

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Department of research and technology of Tehran
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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**

Tehran University of Medical Sciences

Full name of responsible person

Ali Hossein Ghasemi

Position

PhD student

Latest degree

Master

Other areas of specialty/work

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Professor

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Latest degree

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to

make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The results of the present study will be shared in more
than one articles and thesis format

When the data will become available and for how long

After the end of sampling and statistical analysis, the
results will be available as more than one article and
thesis.

To whom data/document is available

Academic researchers, physiotherapists

Under which criteria data/document could be used

For clinical using, systematic review and meta-analysis

From where data/document is obtainable

The results will be available as article and thesis.

What processes are involved for a request to access data/document

After the end of sampling and statistical analysis, the
results will be available as articles and thesis.

Comments

The researchers plan to publish the results of this study
in more than one article.