Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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, elecrophysiologic 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)

Phone
+98 912 500 5401

Email address
olyaeigh@tums.ac.ir

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 coricosteriod 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

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

City
Tehran

Province
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

Street address
Hasan Abad Square; Imam Khomeini Ave

City
Tehran

Province
Tehran

Postal code
1136746911

Phone
+98 21 6634 8500

Email
ghasemi.amirhossien@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Akbar Fotoohi

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

City
Tehran

Province
Tehran

Postal code
3439123900

Phone
+98 21 8163 3685

Email
ghasemi.amirhossien@yahoo.com

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
Physiotherapy

Street address
School of Rehabilitation of Tehran University of Medical Science; Piche Shemiran; Enghelab street

City
Tehran

Province
Tehran

Postal code
1148956111

Phone
+98 21 7752 8468

Email
ghasemi.amirhossien@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Gholamreza Olyaei

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
School of rehabilitation of Tehran University of Medical Science; Piche Shemiran; Enghelab street

City
Tehran

Province
Tehran

Postal code
1148956111

Phone
+98 21 7752 8468

Email
olyaeigh@tums.ac.ir

Person responsible for updating data

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
Physiotherapy
Street address
School of rehabilitation of Tehran University of Medical Science; Piche Shemiran; Enghelab street
City
Tehran
Province
Tehran
Postal code
1148956111
Phone
+98 21 7752 8468
Email
ghasemi.amirhossien@yahoo.com

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.