Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of the low-power laser combined with ultrasound in the treatment of carpal tunnel syndrome

Protocol summary

Study aim
Determination of effect of the low-power laser combined with ultrasound in the treatment of carpal tunnel syndrome

Design
Randomized controlled, single-blinded, and parallel-group design study

Settings and conduct
Patients with CTS will randomize into three groups (laser, ultrasound and laser with ultrasound). All patients will receive a wrist orthosis. one group undergo lasre therapy (with wavelength of 830 nm and at a dose of 9 J/cm2 on two points of 2 cm2) , the second group undergo ultrasound therapy (15 minutes per session to the area over the carpal tunnel at a frequency of 1 MHz and an intensity of 1.0 W/cm2, with pulsed mode duty cycle of 1:4)and the third group undergo laser with ultrasound therapy.

Participants/Inclusion and exclusion criteria
Patients with carpal tunnel syndrome Phalen test positive Tonel test positive Prolonged nerve conduction velocity

Intervention groups
Laser therapy, low-power diode laser, with wavelength of 830 nm and at a dose of 9 J/cm2 on two points of 2 cm2 over the transverse ligament for two weeks as 5 sessions per week. Ultrasound treatment, 15 minutes per session to the area over the carpal tunnel at a frequency of 1 MHz and an intensity of 1.0 W/cm2, with pulsed mode duty cycle of 1:4 and a transducer area of 5 cm2 for two weeks as 5 sessions per week. Laser with ultrasound therapy, Laser (similar to the Lasre group) follow by ultrasound (similar to the ulrtasound group) for for two weeks as 5 sessions per week.

Main outcome variables
Visual Analog Scale, distal sensory and motor latencies of the median nerve

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190202042581N1**
Registration date: **2019-02-14, 1397/11/25**
Registration timing: **prospective**

Last update: **2019-02-14, 1397/11/25**
Update count: **0**

Registration date
2019-02-14, 1397/11/25

Registrant information

Name
Mohammad Reza Asadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 81 3423 0949

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-21, 1398/02/01

Expected recruitment end date
2020-09-21, 1399/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of the low-power laser combined with ultrasound in the treatment of carpal tunnel syndrome

Public title
The effect of the low-power laser combined with ultrasound in the treatment of carpal tunnel syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients diagnosed with mild to moderate carpal tunnel syndrome The grades of the CTS were scrutinized using electrodiagnostic findings as the grades 0-3 were mild to moderate and grades 4-6 were identified as severe Phalen and Tinel test positive
Exclusion criteria:
cervical radiculopathy Thoracic outlet syndrome Peripheral neuropathy
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible participants were randomly randomly divided, using the table of random numbers,into three groups of trials including: Groups of US, Laser and laser with US. Concealment of allocation was performed using sequentially numbered, sealed, opaque, stapled envelopes. The randomization was per-formed by primary investigator.
Blinding (investigator's opinion)
Single blinded
Blinding description
The patients were blinded to the treatment allocation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamedan University of Medical Sciences
Street address
Hamedan University of Medical Sciences, Fahmideh Blvd
City
Hamedan
Province
Hamadan
Postal code
6517838736
Approval date
2019-01-26, 1397/11/06
Ethics committee reference number
IR.UMSHA.REC.1397.790

Health conditions studied

1

Description of health condition studied
Carpal tunnel syndrom
ICD-10 code
S64.1
ICD-10 code description
Injury of median nerve at wrist and hand level

Primary outcomes

1

Description
pain severity
Timepoint
First session (before intervention), 10 and 21 day (after intervention)
Method of measurement
Visual Analogue Scale

2

Description
Distal motor latency of median nerve
Timepoint
First session and last session
Method of measurement
Electrodiagnostic set up

3

Description
Distal sensory latency of median nerve
Timepoint
First session and last session
Method of measurement
Electrodiagnostic set up

Secondary outcomes

1

Description
Hand grip strength
Timepoint

First session and last session

Method of measurement

Dynamometer

2

Description

Pinch strength

Timepoint

First session and last session

Method of measurement

Dynamometer

Intervention groups

1

Description

First Intervention group: laser therapy: low-power diode laser, with wavelength of 830 nm and at a dose of 9 J/cm2 on two points of 2 cm2 over median nerve, in wrist area, for two weeks (10 session) as 5 sessions per week.

Category

Rehabilitation

2

Description

Second Intervention group: ultrasound therapy: Ultrasound treatment including: 15 minutes per session to the area over the carpal tunnel at a frequency of 1 MHz and an intensity of 1.2 W/cm2, with pulsed mode duty cycle of 1:4 and a transducer area of 5 cm2 for two weeks (10 sessions) as 5 sessions per week.

Category

Rehabilitation

3

Description

Third Intervention group: laser therapy with ultrasound therapy: Laser therapy (similar to the Lasre group) follow by ultrasound therapy (similar to the ulrtasound group) for two weeks (10 session) as 5 sessions per week.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Mobasher clinic

Full name of responsible person

Mohammad Reza Asadi

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Mahdieh Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

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?

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Mohammad Reza Asadi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

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Position
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Other areas of specialty/work
Physiotherapy

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Person responsible for updating data

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Position
Assistant professor

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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
No more 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
Not applicable

Data Dictionary
Not applicable