Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effectiveness of shock wave therapy versus phonophoresis on improvement of clinical symptoms and function of patients with mild and moderate carpal tunnel syndrome

Protocol summary

Study aim

The effectiveness of shock wave therapy versus phonophoresis on improvement of clinical symptoms and function of patients with mild and moderate carpal tunnel syndrome(CTS)

Design

A randomized controlled clinical trial with three parallel, double-blind groups

Settings and conduct

Sampling was done by non-probability sequential method. Sixty CTS patients were selected from patients referred to physical medicine clinics of Al-Zahra, Kashani, Issa bin Maryam and Khorshid hospitals in Isfahan, Iran. Controls).Patients were unaware of the research and statistical purposes of the study and how the treatments were compared, and data were provided to the data analyzer after being anonymized.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with mild to moderate CTS who had mild to moderate CTS based on sensory and motor CTS examinations, Tinel and Falen tests, and electrodiagnostic findings. Willingness to participate in the study Non Inclusion criteria: Corticosteroid injection at 3 months prior to study Physical or medicinal modalities in the past 3 months Underlying conditions such as hypothyroidism, diabetes mellitus, rheumatic diseases, wrist arthritis, acute trauma or pregnancy Ultrasound and in vivo shock (pregnancy, acute inflammation, plastic implant, near pacemaker, on epiphysis, near the spinal cord or laminectomy site) History of surgery or fracture of the wrist area

Intervention groups

This study was performed on three groups of 20 patients. A sham vivo treatment group (with splint), a phonophoresis treatment (with splint), and a control group were treated with splint and medication to assess pain and function before treatment, one and two months after treatment, and evaluated with each other. compared.

Main outcome variables

Pain, Function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171230038142N10**
Registration date: **2019-08-17, 1398/05/26**
Registration timing: **retrospective**

Last update: **2019-08-17, 1398/05/26**
Update count: **0**

Registration date

2019-08-17, 1398/05/26

Registrant information

Name

Khosro Tavakol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 9134

Email address

tavakol@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-06, 1398/02/16

Expected recruitment end date

2019-06-06, 1398/03/16

Actual recruitment start date

2019-05-06, 1398/02/16

Actual recruitment end date

2019-06-10, 1398/03/20

Trial completion date

2019-06-10, 1398/03/20

Scientific title

The effectiveness of shock wave therapy versus phonophoresis on improvement of clinical symptoms and function of patients with mild and moderate carpal tunnel syndrome

Public title

The effectiveness of shock wave therapy versus phonophoresis on improvement of clinical symptoms and function of patients with carpal tunnel syndrome(CTS)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who had mild to moderate CTS with sensory and motor examinations, Tinel and Falun tests, and electrodiagnostic findings for more than a month. Willingness to participate in the study

Exclusion criteria:

Corticosteroid injection at least 3 months before the study Physical or medicinal modalities in the past 3 months Underlying conditions such as hypothyroidism, diabetes mellitus, rheumatic diseases, wrist arthritis, acute trauma or pregnancy Ultrasound and in vivo shock (pregnancy, acute inflammation, plastic implant, near pacemaker, on epiphysis, near the spinal cord or laminectomy site) History of surgery or fracture of the wrist area

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling was done by non-probability sequential method. Sixty CTS patients were selected from patients referred to physical medicine clinics of Al-Zahra, Kashani, Issa bin Maryam and Khorshid hospitals in Isfahan, Iran. Controls).

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients were unaware of the research and statistical purposes of the study and how the treatments were compared, and data were provided to the data analyzer after being anonymized.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib Ave., Isfahan University of Medical Sciences.

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2019-05-05, 1398/02/15

Ethics committee reference number

IR.MUI.MED.REC.1398.035

Health conditions studied

1

Description of health condition studied

Carpal Tunnel Syndrome

ICD-10 code

S64

ICD-10 code description

Injury of nerves at wrist and hand level

Primary outcomes

1

Description

Pain

Timepoint

Before, one month and two months after intervention

Method of measurement

Using Visual Analogue Scale questionnaire

2

Description

Function

Timepoint

Before, one month and two months after intervention

Method of measurement

Using the Bostone Status and Performance Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Includes 20 patients with carpal tunnel syndrome who in addition to thermoplastic varicella splint at 0 to 5 degrees extension for 4 weeks for overnight use and vitamin B1 tablet 300 mg daily for 30 days, 4 sessions of focus view shock, starting With energy of 0.05 and increase based on patient and protocol tolerance up to 0.07, 0.1 and 0.15 as well as start with shock number 800 and increase based on patient tolerance and protocol up to 900, 1000 and 1100 and with frequency They received 3 Hz per session.

Category
Treatment - Devices

2

Description
Intervention group: Includes 20 patients with carpal tunnel syndrome who, in addition to thermoplastic splenic splint at 0 to 5 degrees of extension for 4 weeks for overnight use and vitamin B1 tablets 300 mg daily for 30 days, for two weeks, one day between and Each day for 15 minutes, they were pulsed (1 to 4) with 1 MHz frequency and 1 w / cm2 with 1% hydrocortisone ointment.

Category
Treatment - Devices

3

Description
Control group: Including 20 patients with carpal tunnel syndrome who received only thermoplastic varicella splint at 0 to 5 degrees for 4 weeks for overnight use and vitamin B1 tablets 300 mg daily for 30 days.

Category
Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Kashani Hospital in Isfahan

Full name of responsible person
Shila Haghighat

Street address
Kashani Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
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dean@med.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Shila Haghighat

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Physical Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All information is shared after anonymity and two years after the results are published.
When the data will become available and for how long
two years after the results are published
To whom data/document is available
Physicians and specialists in the field of physical medicine and rehabilitation
Under which criteria data/document could be used
Comparison of existing methods with new methods or drugs
From where data/document is obtainable
Email Haghighatshila@gmail.com and obtain permission from Isfahan University of Medical Sciences.
What processes are involved for a request to access data/document
Send request by email to Haghighatshila@gmail.com and obtain permission from Isfahan University of Medical Sciences.
Comments