

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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

Isfahan

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

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3670 0666

Email

Haghighatshila@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ziba Farajzadegan

Street address

Vice-Chancellor for Research of School of Medicine,.
Isfahan University of Medical Sciences,. Hezar Jarib
Ave.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 8597

Email

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

Street address

Isfahan University of Medical Sciences, Hezar Jerib

Ave.
City
Isfahan
Province
Isfahan
Postal code
8174675731
Phone
+98 31 3670 0666
Email
Haghighatshila@gmail.com

Person responsible for scientific 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
Street address
Isfahan University of Medical Sciences, Hezar Jerib Ave.
City
Isfahan
Province
Isfahan
Postal code
8174675731
Phone
+98 31 3670 0666
Email
Haghighatshila@gmail.com

Person responsible for updating data

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
Street address
Isfahan University of Medical Sciences, Hezar Jerib Ave.
City
Isfahan
Province
Isfahan
Postal code
8174675731
Phone
+98 31 3670 0666
Email
Haghighatshila@gmail.com

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