

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of focus shockwave and radial shockwave on the improvement of clinical symptoms and function in patients with carpal tunnel syndrome

Protocol summary

Study aim

Determination and comparison of radial shockwave methods in comparison with focus shock shockwave in improving clinical symptoms and function of patients with carpal tunnel syndrome

Design

The clinical trial, with parallel groups, single-blind, randomized, phase 2 on 40 patients

Settings and conduct

In this randomized Single-blind clinical trial study, 40 patients with carpal tunnel syndrome referred to Al-Zahra Hospital in Isfahan will be included in the study and randomly divided into two groups. One group is exposed to radial shockwave and the other group is exposed to focus shockwave. It is necessary to mention that the patient and the person recording the patient's clinical information and the statistical analyst will not be aware of the type of intervention. Then the disease severity score, functional status, and pain of patients will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria included age over 18 years, carpal tunnel syndrome with mild to moderate severity, complete all treatment sessions, and consent to participate in the study. Exclusion criteria included severe carpal tunnel syndrome, having diseases that mimic the symptoms of carpal tunnel syndrome, pregnancy, having diabetes, coagulation disorders, history of wrist fractures and dislocations, opioid use, and taking herbal medicines and complementary medicine.

Intervention groups

Intervention group 1: In this group, sham focus with radial shockwave in the carpal tunnel area is done one session per week for 3 weeks. Second intervention group: In this group, radial sham with focus shockwave in the carpal tunnel area is done one session per week for 3

weeks.

Main outcome variables

Disease severity score; Functional status score; Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N38**

Registration date: **2021-08-21, 1400/05/30**

Registration timing: **prospective**

Last update: **2021-08-21, 1400/05/30**

Update count: **0**

Registration date

2021-08-21, 1400/05/30

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-22, 1400/05/31

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of focus shockwave and radial shockwave on the improvement of clinical symptoms and function in patients with carpal tunnel syndrome

Public title

The effect of two shockwave focus and radial on the recovery of patients with carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 years Carpal tunnel syndrome with mild to moderate severity approved by a physician based on clinical examination and standard electrodiagnostic criteria Complete all treatment sessions (once a week for up to three weeks) consent to participate in the study

Exclusion criteria:

Severe carpal tunnel syndrome (Severe) Having diseases that mimic the symptoms of carpal tunnel syndrome, such as cervical radiculopathy, peripheral neuropathy, and median nerve trauma Pregnancy Having diabetes History of wrist fractures and dislocations History of hand surgery in the last 6 months Warfarin use or hereditary or acquired coagulation disorders Opioid use Taking herbal medicines and complementary medicine

AgeFrom **18 years** old**Gender**

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **40****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, 40 eligible patients will be randomly selected. Then random numbers are created by computer software "Random Allocation". We randomly divide these numbers into two parts. Each number is written on paper and placed in an envelope. Then each patient is asked to choose an envelope from among the envelopes. According to the selected envelope, the patient will be assigned to one of the two groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the different shockwave in this study, the researcher is aware of the type of intervention in each group. However, the patient and the person recording the patient's clinical information and the statistical

analyst will not be aware of the type of intervention.

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

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfahan

Postal code

8179964167

Approval date

2020-11-13, 1399/08/23

Ethics committee reference number

IR.MUI.MED.REC.1399.712

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**

Disease severity score

Timepoint

Before the intervention, three weeks and three months after the intervention

Method of measurement

The Boston Carpal Tunnel Questionnaire (BCTQ)

Secondary outcomes**1****Description**

Functional status score

Timepoint
Before the intervention, three weeks and three months after the intervention

Method of measurement
The Boston Carpal Tunnel Questionnaire (BCTQ)

2

Description
Pain

Timepoint
Before the intervention, three weeks and three months after the intervention

Method of measurement
The Boston Carpal Tunnel Questionnaire (BCTQ)

Intervention groups

1

Description
Intervention group 1: In this group, sham focus with radial shockwave (3000 shocks, intensity 3 bar and frequency HZ 10) in the carpal tunnel area is done one session per week for 3 weeks.

Category
Treatment - Other

2

Description
Second intervention group: In this group, radial sham with shockwave focus (3000 shocks, intensity 1 J/cm² and frequency 3 HZ) in the carpal tunnel area is done one session per week for 3 weeks.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-Zahra Hospital

Full name of responsible person
Babak Vahdatpour

Street address
Department of Physical Medicine and Rehabilitation, Al-Zahra Hospital, Sofeh Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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?
No

Title of funding source
Isfahan 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
Babak Vahdatpour

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Physical Medicine

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Person responsible for scientific inquiries

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Position
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Latest degree
Subspecialist
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Person responsible for updating data

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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

There is no further 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available