Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of shockwave therapy and steroid injection on sonographic and electrodiagnostic findings in carpal tunnel syndrome

Protocol summary

Study aim

Comparison of the effect of shockwave therapy and steroid injection on sonographic and electrodiagnostic findings in carpal tunnel syndrome...

Design

Two-group clinical trial, with parallel, randomized groups, on 60 patients. Random blocking method was used for randomization.

Settings and conduct

In this prospective and randomized clinical trial study, patients with signs and symptoms of carpal tunnel syndrome (including pain and sensory disturbances in the median nerve area) went to the specialized clinic of physical medicine and rehabilitation of Firoozgar and Hazrat Fatemeh Hospital. (PBUH) and Hazrat Rasool (PBUH) Hospital are referred and their disease is confirmed by EMG-NCS and according to electrodiagnostic criteria, they have mild to moderate carpal tunnel syndrome.

Participants/Inclusion and exclusion criteria

Patients with signs and symptoms of carpal tunnel syndrome (including pain and sensory disturbances in the median nerve area) referred to the clinic and according to electrodiagnostic criteria with mild to moderate carpal tunnel syndrome were included in the study and patients with severe carpal tunnel syndrome (based on Electrodiagnosis data) and signs of atrophy of the thenar muscles were excluded from the study.

Intervention groups

Group A Patients: In group A, corticosteroid injections will be performed under ultrasound guidance, under sterile conditions and using the free hand technique. Group B Patients: Each patient in the radial shock wave treatment group receives two rounds of treatment one week apart with the characteristics of severity, frequency, number of shocks, and the type of device: 1.5 Bar, 6 Hz frequency, 2000 shocks For both groups, the standard treatment will be 6 weeks using a wrist splint.

Main outcome variables

Boston Questionnaire Score, visual analogue score for pain (VAS), EDX Criteria, Ultrasound Criteria, Injection Complications

General information

Reason for update

Due to the covid-19 pandemic and also the start of sampling after the finalization of the trial registration in the Iranian Clinical Trial Registration Center, the start and end dates of sampling and also the number of samples per person were updated. In both intervention groups, standard wrist splint treatment will be performed for six weeks. In the shockwave therapy intervention group, the device intensity profile was performed from 2 to 1.5 due to better patient tolerance as well as similar proven effects in studies with this intensity. The sampling site of Hazrat Rasool Akram Hospital was updated.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200824048503N1**
Registration date: **2020-09-25, 1399/07/04**
Registration timing: **prospective**

Last update: **2020-12-03, 1399/09/13**
Update count: **1**

Registration date

2020-09-25, 1399/07/04

Registrant information

Name
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2020-12-03, 1399/09/13

Expected recruitment end date
2021-02-01, 1399/11/13

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of shockwave therapy and steroid injection on sonographic and electrodiagnostic findings in carpal tunnel syndrome

Public title
Comparison of the effect of shock wave therapy and steroid injection in carpal tunnel syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Referrals of patients with signs and symptoms of carpal tunnel syndrome (including pain and sensory disturbances in the area of the median nerve) Patients with mild to moderate carpal tunnel syndrome according to electrodiagnostic criteria

Exclusion criteria:
Severe carpal tunnel syndrome (based on electrodiagnosis data). Symptoms of atrophy of Tanar area Contraindications to corticosteroid injections (including allergy to corticosteroids and symptoms of skin infection at the injection site, local abscess at the injection site, patients with immunodeficiency, phobia to needles) Diseases that mimic the symptoms of CTS, such as polyneuropathy, cervical radiculopathy, thoracic outlet syndrome, Surgical treatment or topical injection in the last six months Neoplastic or traumatic origin of pain and fracture of wrist bones Age under 18 years

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **1**
Depending on whether one or both wrists are involved, each participant may provide one or two samples.

Randomization (investigator's opinion)
Randomized

Randomization description
After sampling, which will be easy as sampling, patients will be randomly (using random blocking method) in one of the two groups of 40 mg triamcinolone topical injection under the guidance of sonography and shock wave treatment.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Iran University of Medical Sciences

Street address
Iran University of Medical sciences, Hemmat Highway

City
Tehran

Province
Tehran

Postal code
8739118631

Approval date
2020-07-14, 1399/04/24

Ethics committee reference number
IR.IUMS.FMD.REC.1399.272

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
Electrodiagnostic criteria in the study

Timepoint
For subjective evaluation of efficacy and comparison of corticosteroids with shock wave therapy method, two criteria Visual Analogue Scale and Boston questionnaire and for objective evaluation of effectiveness and comparison of two methods, electrodiagnostic and sonographic criteria will be used in zero, 2 weeks, and It will be measured for 6 months.

Method of measurement

Electro-diagnostic assessment will conduct with Natus (Synergy ultrapro S100) device by a physical medicine specialist for all patients. The diagnostic criteria of Carpal Tunnel Syndrome based on electrodiagnostic findings included: Distal latency of median sensory nerve action potential (SNAP) of third finger <3.6 and distal latency of median compound muscle action potential(CMAP) of abductor pollicis brevis (APB) muscle <4.2. If only the SNAP distal latency was long, patient had mild CTS, but if both SNAP and CMAP distal latency were long and denervation was not observed in electromyography of abductor pollicis brevis, it was moderate Carpal Tunnel Syndrome. The needle electromyography will be performed for other muscles of upper limbs to roll out other diagnosis for example : cervical radiculopathies , plexopathies and other median nerve entrapments.

2

Description

Sonographic Evaluation

Timepoint

For subjective evaluation of efficacy and comparison of corticosteroids with shock wave therapy method, two criteria Visual Analogue Scale and Boston questionnaire and for objective evaluation of effectiveness and comparison of two methods, electrodiagnostic and sonographic criteria will be used in zero, 2 weeks, and It will be measured for 6 months.

Method of measurement

Median nerve Ultra Sound evaluation images will obtain by a physical medicine specialist for all patients . Images will collect on the same day as Electrodiagnostic testing by using a Hitachi (2015-JAPAN-Arietta v 60 j) equipped with an 18–5 MHz linear array transducer. The median nerve will image in cross section at the distal wrist crease (carpal tunnel inlet) . The cross-sectional area (CSA) was calculated using the continuous trace method by outlining the perimeter just inside the hyperechoic epineurium. Three measurements will be made for each person and the average will be considered for analysis.

3

Description

Visual Analogue Scale

Timepoint

For subjective evaluation of efficacy and comparison of corticosteroids with shock wave therapy method, two criteria Visual Analogue Scale and Boston questionnaire and for objective evaluation of effectiveness and comparison of two methods, electrodiagnostic and sonographic criteria will be used in zero, 2 weeks, and It will be measured for 6 months.

Method of measurement

The visual scale for measuring pain intensity is a 10 cm ruler with the word painless written on the left end and the word "most severe pain" written on the right end. Continuity marks. Note that they only mark one point. The amount of pain was measured by the researcher using the Visual-Linear Pain Scale (VAS), which is standardized for measuring pain. The linear-visual pain measurement scale is divided from zero to ten as follows:0-1: No pain, 2-3: Low pain, 4-5: High pain, 6-7: Very bad pain, 8-9: Maximum pain, 10: unbearable pain

4

Description

Boston Carpal Tunnel Syndrome Questionnaire (BCTQ)

Timepoint

For subjective evaluation of efficacy and comparison of corticosteroids with shock wave therapy method, two criteria Visual Analog Scale and Boston questionnaire and for objective evaluation of effectiveness and comparison of two methods, electrodiagnostic and sonographic criteria will be used in zero, 2 weeks, and It will be measured for 6 months.

Method of measurement

The Boston questionnaire is self-applied and evaluates the severity of symptoms and the functional status of patients with carpal tunnel syndrome. The symptoms severity scale evaluates symptoms regarding severity, frequency, time and kind. The functional status scale evaluates how the syndrome affects daily life .Questions concerning symptoms severity scale are composed of 11questions addressing: pain intensity during daytime and nighttime, time of pain during the day, dormancy ,weakness, tingling sensation at night, frequency of that night tingling sensation, and skill. Each question has five answers numbered from 1 to 5, arranged in an increasing order of symptoms severity. Therefore, 1 means no symptoms, 2 mild symptoms, 3 moderate symptoms,4 intense symptoms, and 5 severe symptoms .Questions concerning functional status are composed of 8 questions, where each one corresponds to afunctional activity (writing, buttoning clothes, holding a book while reading, holding a telephone hang, housekeeping, opening a glass vial cap, carrying market bags, bathing and dressing).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Forty mg triamcinolone topical injection group under ultrasound guidance with one injection Also use a wrist splint for 6 weeks

Category

Treatment - Drugs

2

Description

Intervention group: Radial shock wave treatment group, Each patient in the Wave Radial shock treatment group receives two rounds of treatment one week apart with the characteristics of intensity, frequency, number of shocks and the type of device: 2 Bar, 6 Hz frequency, 2000 shocks TYPE OF MACHINE: (BTL-6000 SWT, RADIAL

shockwave mode The probe is placed perpendicular to the patient's palm area between the distal crease of the wrist and Kaplan's cardinal line. Ultrasound gel is used as a binding agent. Also use a wrist splint for 6 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrate Fatemeh(S) Hospital
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2

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3

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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
Iran 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
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Hawre Morovati

Position
Consultant

Latest degree
Medical doctor

Other areas of specialty/work
Physical Medicine

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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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Part of the data, such as information about the main outcome, can be shared.

When the data will become available and for how long
Access period starts from the winter of 1399

To whom data/document is available
For researchers working in academic and scientific institutions

Under which criteria data/document could be used
No analysis is allowed on the delivered data.

From where data/document is obtainable
Mail

What processes are involved for a request to access data/document
Request via email

Comments