Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effect of two methods of point and switch radial shock wave therapy on pain intensity and electrophysiological parameters of median nerve in patients with carpal tunnel syndrome

Protocol summary

Study aim

1. Comparing the effect of two methods of point and switch radial shock wave therapy on pain intensity, hand function, sensory distal latency and motor distal latency
2. Comparing the effect of two methods of point / switch radial shock wave therapy and routine physiotherapy on pain intensity, hand function, sensory distal latency and motor distal latency

Design

A clinical trial with parallel group trial, double blinded with simple randomization.

Settings and conduct

Patients with mild to moderate carpal tunnel syndrome that referred to neurology clinic of Ayatollah Rouhani Hospital in Babol city. They are first examined by a neurologist, then we select 60 patients with consideration of inclusion and exclusion criteria of study.

Participants/Inclusion and exclusion criteria

Positive Phalen's test and compression test in physical examination Paresthesia, numbness or pain for more than 3 months Visual analogue scale (VAS) ≥ 3 and VAS < 6 Confirmed diagnosis of mild to moderate CTS with electrophysiological study

Intervention groups

Routine physiotherapy protocol: include transcutaneous nerve electrical stimulation, ultrasound therapy and short cock up splint and vitamin B1 300 mg Point group protocol: patients will receive routine physiotherapy protocol with 4 sessions of shock wave therapy with point application of shock wave. Switch group protocol: patients will receive routine physiotherapy protocol with 4 sessions of shock wave therapy with switch application of shock wave.

Main outcome variables

Pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200706048028N1**
Registration date: **2020-08-24, 1399/06/03**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-24, 1399/06/03**
Update count: **0**

Registration date

2020-08-24, 1399/06/03

Registrant information

Name
Yahya Javadian
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-29, 1399/05/08

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the effect of two methods of point and switch radial shock wave therapy on pain intensity and electrophysiological parameters of median nerve in patients with carpal tunnel syndrome

Public title
Comparing the effect of two methods of radial shock wave therapy in patients with carpal tunnel syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients 20-70 years of age with tingling and numbness or hand pain more than 3 month and confirmed mild to moderate carpal tunnel syndrome by electrophysiological study

Exclusion criteria:

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants are divided into three groups using simple randomization method

Blinding (investigator's opinion)
Double blinded

Blinding description
The investigators who evaluate the electrodiagnostic and clinical measurements will blind to the allocation and to each other, The patients are blinding too.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Babol University of Medical Sciences

Street address
Babol university of medical sciences, Ganjafrooz Street , Babol , Mazandaran ,Iran

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47176-47745

Approval date
2020-07-05, 1399/04/15

Ethics committee reference number
IR.MUBABOL.HRI.REC.1399.106

Health conditions studied

1

Description of health condition studied
Mild to moderate Carpal Tunnel Syndrome

ICD-10 code
G56.00

ICD-10 code description
Carpal tunnel syndrome, unspecified upper limb

Primary outcomes

1

Description
Pain intensity

Timepoint
Before intervention, after intervention and 1 month after intervention

Method of measurement
The visual analog scale (VAS) was used to evaluate the degree of pain, which was self assessed by the patients, and the scale ranges from 0 to10

Secondary outcomes

1

Description
Evaluating symptoms severity and functional status of hand

Timepoint
Before intervention, after intervention and 1 month after intervention

Method of measurement
The Boston questionnaire consists of a symptoms severity scale (SSS) and a functional status scale (FSS), and it was answered by the patients. SSS is evaluated by 11 questions concerning pain, tingling, night symptoms, numbness, and hand weakness and responses range from no symptoms (1point) to symptoms too severe to perform activity (5 point). The average of these 11 scores was used to quantify the severity of patients' symptoms. FSS consists of 8 questions concerning functional activities and responses range from functional activities with less deficiency (1 point) to functional activities with high deficiency (5 point). The average of these 8 scores was used to quantify the patients' functional status.

2

Description
sensory and motor distal latency
Timepoint
Before and after intervention
Method of measurement
EDX evaluating (Nerve Conduction Study)

Intervention groups

1

Description
Routine physiotherapy group: Patients in this group receive routine physiotherapy including patient education, TENS, therapeutic ultrasound 3 days a week for 10 sessions and ask them to use short cock-up splint and vitamin B1 300 mg.TENS administer for 20 min each session, at a frequency of 80 HZ, with a pulse duration of 60 µs and at intensity that produce a comfortable tingling sensation. negative electrode is placed on carpal tunnel, and positive electrode is placed on palmar surface of hand.Therapeutic ultrasound administer to the palmar carpal tunnel area for 5 min per session, at a frequency 1 MHZ with intensity of 1 W/cm2 and duty cycle of 50%. we instruct patients to wear the short cock-up splint at night for two weeks and ask them to consumption of vitamin B1 300 mg each day for 4 weeks.
Category
Rehabilitation

2

Description
Point shock wave therapy group: patients in this group receive routine physiotherapy including patient education, TENS, therapeutic ultrasound 3 days a week for 10 sessions and ask them to use short cock-up splint and vitamin B1 300 mg exactly similar to routine group, in addition to the aforementioned routine physiotherapy, patient in the point shock wave therapy group receive shock wave therapy for 4 sessions as described below.for shock wave therapy, patients sit in a relax position with their forearm and finger resting on the table. with the palm facing up, the shock wave probe places perpendicularly on patients palm over the median nerve on carpal tunnel after application of the coupling gel. the median nerve is localized by anatomic landmarks on the wrist (scaphoid-pisiform level). shock wave administrate without anesthesia using a pneumatic generator (STORZ Medical Masterpuls MP100, Tagerwilen, switzerland) with 1500 shocks, at a pressure of 1/5 Bar and a rate of 6 pulse per second with point application (hold probe of shock wave stationary over the carpal tunnel).
Category
Rehabilitation

3

Description
Switch shock wave therapy group: patients in this group receive routine physiotherapy including patient education, TENS, therapeutic ultrasound 3 days a week for 10 sessions and ask them to use short cock-up splint and vitamin B1 300 mg exactly similar to routine group, in addition to the aforementioned routine physiotherapy, patient in the point shock wave therapy group receive shock wave therapy for 4 sessions as described below.for shock wave therapy, patients sit in a relax position with their forearm and finger resting on the table. with the palm facing up, the shock wave probe places perpendicularly on patients palm over the median nerve on carpal tunnel after application of the coupling gel. the median nerve is localized by anatomic landmarks on the wrist (scaphoid-pisiform level). shock wave administrate without anesthesia using a pneumatic generator (STORZ Medical Masterpuls MP100, Tagerwilen, switzerland) with 1000 shocks, at a pressure of 1/5 Bar and a rate of 6 pulse per second with point application (hold probe of shock wave stationary over the carpal tunnel), and 500 shocks are applied with switch application (switch shock wave's probe on median nerve pathways on palmar surface of hand).
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Rouhani hospital in Babol city
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Sponsors / Funding sources

1

Sponsor
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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
Babol 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
Babol University of Medical Sciences

Full name of responsible person
Atieh Habibzadeh

Position
Master Student

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Bachelor

Other areas of specialty/work
Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

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