

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

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3223 8307

Email address

javad835@yahoo.com

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

City

Babol

Province

Mazandaran

Postal code

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 μ s 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

Full name of responsible person

Yahya Javadian

Street address

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

City

Babol

Province

Mazandaran

Postal code

47176-47745

Phone

+98 11 3219 9592

Email

javad835@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

Street address

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

City

Babol

Province

Mazandaran

Postal code

47176-47745

Phone

+98 11 3219 9952

Email

javad835@yahoo.com

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

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

Floor1, 5 Bldg, Tohid 16 St, Tohid Cross, Babol , Mazandaran ,Iran

City

Babol

Province

Mazandaran

Postal code

66867-47187

Phone

+98 11 3233 7101

Fax

Email

ati.habibzadeh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Yahya Javadian

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

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

City

Babol

Province

Mazandaran

Postal code

47176-47745

Phone

+98 11 3223 8307

Fax

Email

javad835@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Yahya Javadian

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

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

City

Babol

Province

Mazandaran

Postal code

47176-47745

Phone

+98 11 3219 9952

Email

javad835@yahoo.com

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