

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 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)  $\geq 3$  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  $\mu$ 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/cm<sup>2</sup> 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

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Babol University of Medical Sciences

##### **Full name of responsible person**

Reza Ghadimi

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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

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for scientific inquiries

**Contact**

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**Position**

Associate professor

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Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

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**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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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