

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Evaluation of the effect of interventions near and far to the carpal tunnel site using dry needle method and routine physiotherapy on clinical and paraclinical indicators of patients with carpal tunnel syndrome (CTS)

#### Protocol summary

##### Study aim

Comparison of the effect of interventions near and far to the carpal tunnel site using dry needle method and routine physiotherapy on clinical and paraclinical indicators of patients with carpal tunnel syndrome (CTS)

##### Design

Single-blind randomized clinical trial

##### Settings and conduct

The study population is patients with carpal tunnel syndrome whose disease is confirmed by an orthopedic physician and referred to the clinics of Yazd University of Medical Sciences for treatment. After the evaluation, if the patients are eligible to enter the study and if they wish to participate in the study, they will receive the informed consent form approved by the ethics committee of Yazd University of Medical Sciences and fully explain the implementation method to them. Be. The therapist and evaluator are two different people and neither group will be aware of the intervention. Physiotherapy and dry needle treatment and control are similar in all three groups. The intervention in the dry needle group is in the form of dry needle insertion along the upper limb chain and in the routine physiotherapy group is in the form of mobility of the flexor tendons. All three groups will receive guideline treatment, including the use of wrist brace. Patients will be followed up before the intervention and one month after the intervention.

##### Participants/Inclusion and exclusion criteria

Having clinical signs to diagnose carpal tunnel syndrome. At least 6 months (in cases of early diagnosis of mild to moderate carpal tunnel syndrome)

##### Intervention groups

Intervention group one: The group receiving dry needling. Intervention group two: The group receiving routine physiotherapy.

##### Main outcome variables

muscle and fascia thickness; carpal tunnel space; nerve

conduction; score of Boston Carpal Tunnel Questionnaire, visual pain scale.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130612013651N4**

Registration date: **2020-07-23, 1399/05/02**

Registration timing: **prospective**

Last update: **2020-07-23, 1399/05/02**

Update count: **0**

##### Registration date

2020-07-23, 1399/05/02

##### Registrant information

##### Name

Ali Barzegar

##### Name of organization / entity

Yazd University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3233 2091

##### Email address

bafronei@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-08-04, 1399/05/14

##### Expected recruitment end date

2020-10-05, 1399/07/14

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effect of interventions near and far to the carpal tunnel site using dry needle method and routine physiotherapy on clinical and paraclinical indicators of patients with carpal tunnel syndrome (CTS)

**Public title**

Evaluation of the effect of interventions near and far to the carpal tunnel using dry needle method and routine physiotherapy

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having clinical signs to diagnose carpal tunnel syndrome. Have symptoms of the disease in the last 6 months. Age range 20 to 65 years.

**Exclusion criteria:**

Pregnancy. Having a history of carpal tunnel syndrome hand surgery. systemic diseases. Therapeutic intervention has been performed in the last 6 months.

**Age**

From **20 years** old to **65 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **45**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A simple individual randomization method will be used which is only equal in terms of the number of people in each group and the envelope randomization tool is sealed. The groupings are hidden in the envelope in the package, which the intruder accidentally opens by removing the envelope and specifies the grouping. 45 bags including 15 packages of routine physiotherapy, 15 packages of dry acupuncture and 15 packages of control are classified into three groups. The type of intervention in this study is explained to the person who observes the conditions, and if the form of informed consent is completed, it will be included in the study.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The evaluator is the person who collects the data obtained from the intervention or control. The evaluator will not be aware of the random assignment of the groups. Will collect and record the answers based on the defined codes.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Yazd University of Medical Sciences

**Street address**

Shahid sadughi hospital, Shahid ghandi avenue, Yazd

**City**

Yazd

**Province**

Yazd

**Postal code**

8916815235

**Approval date**

2019-06-17, 1398/03/27

**Ethics committee reference number**

IR.SSU.REC.1398.187

**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**

Median nerve conduction velocity

**Timepoint**

Before and after the intervention and one month follow-up interval

**Method of measurement**

electromyography device

**2****Description**

Muscle and fascia thickness

**Timepoint**

Before and after the intervention and follow-up interval

**Method of measurement**

sonography

## Secondary outcomes

### 1

#### Description

pain intensity

#### Timepoint

Before and after the intervention and follow-up interval

#### Method of measurement

Visual analogue scale

### 2

#### Description

Functional ability

#### Timepoint

Before and after the intervention and follow-up interval

#### Method of measurement

Boston Questionnaire

## Intervention groups

### 1

#### Description

Dry needle intervention group: In this group, patient receives dryneedle for 20 minutes. Dry needling is performed on the muscles of Palmaris longus, pronator of fear, flexor digitorum, biceps brachii and pectoralis major after disinfection of the site and using a disposable needle with the same depth and angle by an acupuncturist. During the intervention, the patient uses a wrist brace simultaneously throughout the night and as much as possible daily.

#### Category

Treatment - Other

### 2

#### Description

Routine physiotherapy intervention group: Flexor tendon gliding exercises of the fingers and median nerve gliding are repeated 10 times, held for 5 seconds, and 3 sessions per week for 2 weeks. During the intervention, the patient uses a wrist brace simultaneously throughout the night and as much as possible daily.

#### Category

Treatment - Other

### 3

#### Description

Control group: The patient uses the wrist brace all night and as much as possible daily.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

#### Name of recruitment center

Shahid sadughi hospital

#### Full name of responsible person

Ali Barzegar

#### Street address

Shahid sadughi hospital, Shahid ghandi avenue

#### City

Yazd

#### Province

Yazd

#### Postal code

8916815235

#### Phone

+98 35 3827 6825

#### Email

barzegarali66@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research, Yazd University of Medical Sciences

##### Full name of responsible person

Dr. Masoud Mirzaei

##### Street address

Yazd University of Medical Sciences, Yazd, Iran

##### City

Yazd

##### Province

Yazd

##### Postal code

8916189165

##### Phone

+98 35 3724 0171

##### Email

info@ssu.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice Chancellor for Research, Yazd 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**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
Ali Barzegar  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Physiotherapy  
**Street address**  
Shahid sadughi hospital, Shahid ghandi avenue  
**City**  
Yazd  
**Province**  
Yazd  
**Postal code**  
8916815235  
**Phone**  
+98 35 3827 6825  
**Email**  
barzegarali66@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
Ali Barzegar  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Physiotherapy  
**Street address**  
Shahid sadughi hospital, Shahid ghandi avenue  
**City**  
Yazd  
**Province**  
Yazd  
**Postal code**  
8916815235  
**Phone**

+98 35 3827 6825

**Email**  
barzegarali66@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
Ali Barzegar  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Physiotherapy  
**Street address**  
Shahid sadughi hospital, Shahid ghandi avenue  
**City**  
Yazd  
**Province**  
Yazd  
**Postal code**  
8916815235  
**Phone**  
+98 35 3827 6825  
**Email**  
barzegarali66@gmail.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

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