

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Sensory-motor effects of the dorsal splint which restricts the wrist and finger flexion on patients with carpal tunnel syndrome: a study with parallel groups

#### Protocol summary

##### Study aim

The effect of dorsal splint which restricts wrist and finger flexion in carpal tunnel syndrome on pain relief, symptoms, function, time of patient's symptoms are reproduced in Phalen Test, sense of two-point discrimination, hand dexterity, grip and pinch strength

##### Design

A randomized controlled clinical trial with parallel groups, single-blind

##### Settings and conduct

The target population includes those with mild and moderate carpal tunnel syndrome referred to the Al-Zahra Hospital, diagnosed by an orthopedist. split and study for six weeks. Participants are randomly divided into intervention and control groups. Before and after the interventions, the time of patient's symptoms are reproduced in Phalen Test, pain, symptoms, and function, sense of two-point distinction, hand dexterity, grip, and pinch strength will be measured.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: being over 18 years of age, having positive Phalen maneuvers, didn't have a steroid injection into the carpal canal within the previous 3 months, didn't use any splint before the study, didn't have carpal tunnel release procedure. Exclusion criteria: pregnancy, patients in urgent need of surgery existence of Thenar atrophy or severe carpal tunnel syndrome

##### Intervention groups

Intervention group: Patients who use dorsal splint which restricts the wrist and finger flexion for six weeks.  
Control group: Patients who use a dorsal splint which restricts wrist flexion for six weeks.

##### Main outcome variables

Time of patient's symptoms are reproduced in Phalen Test, Pain, Symptoms, Function, Sense of two-point distinction, hand dexterity, Grip and Pinch strength

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201116049402N1**

Registration date: **2020-11-20, 1399/08/30**

Registration timing: **prospective**

Last update: **2020-11-20, 1399/08/30**

Update count: **0**

##### Registration date

2020-11-20, 1399/08/30

##### Registrant information

##### Name

Zahra Soltani hanafi por

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3821 5062

##### Email address

porya.sol85@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-01-21, 1399/11/02

##### Expected recruitment end date

2021-05-23, 1400/03/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Sensory-motor effects of the dorsal splint which restricts the wrist and finger flexion on patients with carpal tunnel syndrome: a study with parallel groups

## Public title

Effect of dorsal splint which restricts wrist and finger flexion on mild and moderate carpal tunnel syndrome

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Having a positive Phalen maneuver diagnosed with CTS by the physiatrist Being over 18 years of age with mild to moderate symptoms of CTS Didn't use any splints before the study Didn't have a steroid injection into the carpal canal within the previous 3 months Didn't have a carpal tunnel release procedure

### Exclusion criteria:

Pregnancy Patients in urgent need of surgery Existence of Thenar atrophy or sever carpal tunnel syndrome

## Age

From **18 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant

## Sample size

Target sample size: **38**

## Randomization (investigator's opinion)

Randomized

## Randomization description

A simple random sample is a subset of a statistical population in which each member of the subset has an equal probability of being chosen

## Blinding (investigator's opinion)

Single blinded

## Blinding description

A single-blind randomized control trial is when the investigator but not the study participants know which treatment has been allocated.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Esfahan University of Medical Sciences

## Street address

Hezar Jerib St

## City

Esfahan

## Province

Isfahan

## Postal code

8174673461

## Approval date

2020-11-08, 1399/08/18

## Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.547

## 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

Symptoms and Function

#### Timepoint

At baseline and after six weeks

#### Method of measurement

Boston Questionnaire

### 2

#### Description

Pain

#### Timepoint

At baseline and after six weeks

#### Method of measurement

Visual Analog Scale (VAS)

### 3

#### Description

The time it takes to make the Palen Test positive

#### Timepoint

At baseline and after six weeks

#### Method of measurement

Chronometer

### 4

#### Description

Two point discrimination

#### Timepoint

At baseline and after six weeks

#### Method of measurement

Collis

## 5

### Description

Grip and Pinch strength

### Timepoint

At baseline and after six weeks

### Method of measurement

Dynamometer

## 6

### Description

Hand dexterity

### Timepoint

At baseline and after six weeks

### Method of measurement

Nine Hole Peg Test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients who use a dorsal splint which restricts wrist and finger for six weeks

#### Category

Treatment - Devices

### 2

#### Description

Control group: Patients who use a dorsal splint which restricts wrist for six weeks

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Al-Zahra Hospital

##### Full name of responsible person

Ibrahim Sadeghi Demneh

##### Street address

Shahid Keshvari Highway

##### City

Esfahan

##### Province

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##### Postal code

8174673461

##### Phone

+98 31 3668 0048

##### Email

sadeghi@rehab.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Ibrahim Sadeghi Demneh

##### Street address

Hezar Jerib St

##### City

Esfahan

##### Province

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##### Phone

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##### Email

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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

Esfahan 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

Esfahan University of Medical Sciences

##### Full name of responsible person

Ibrahim Sadeghi Demneh

##### Position

Associate professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Technical orthopedics

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Hezarjarib Avenue

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##### Province

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**Email**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Zahra Soltani Hanafipour

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Technical orthopedics

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Zahra Soltani Hanafipour

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Technical orthopedics

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**Province**

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8174673461

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+98 31 3668 0048

**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

**Title and more details about the data/document**

A major part of the information will be available for the population.

**When the data will become available and for how long**

12 months after the publication

**To whom data/document is available**

Available for people working in academic Institutions

**Under which criteria data/document could be used**

To conduct similar studies

**From where data/document is obtainable**

Dr. Ebrahim Sadeghi Demneh sadeghi@rehab.mui.ac.ir

**What processes are involved for a request to access data/document**

The data will send as soon as possible, after receiving the request.

**Comments**