

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Aug 2026

**comparison of the effect of the carpal lock splint and neoprene splint with anterior (palmar)bar on pain and muscle strength in patients with carpal tunnel syndrome.**

### Protocol summary

#### Study aim

Comparison of two therapeutic devices

#### Design

The present study is a comparative clinical trial that uses the VAS table to achieve changes in pain score and the SAEHAN SH5001 dynamometer to measure hand muscle strength. 26 patients will be admitted according to the inclusion criteria.

#### Settings and conduct

Patients with carpal tunnel syndrome referred to Kashani and Al-Zahra Hospital in Isfahan. They will enter the study if they are eligible.

#### Participants/Inclusion and exclusion criteria

Patients 25 to 65 years old, of both sexes, with EMG findings of mild to moderate idiopathic cts. Fallen or positive tunnel test with symptoms such as Pain, numbness, paresthesia, hypostasis in median nerve disorder and Exclusion criteria: Acute hand trauma fracture. Rheumatoid arthritis, diabetes, MS, kidney and thyroid diseases. History of carpal tunnel syndrome surgery. History of steroid injection in the carpal tunnel in the last 3 months. Pregnancy. History of using orthosis. Neuromuscular diseases

#### Intervention groups

We have two intervention groups. In the intervention group, they use "Carpal Lock splint" and in the control group, they use "Neoprene splint with anterior bar", which are our two interventions in the study. In our study, both groups use splints for 4 weeks. Finally, the effect of these two therapies on the mentioned variables is examined and compared.

#### Main outcome variables

"Pain score" and "muscle strength" are our two main variables in the study.

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20211018052800N1**

Registration date: **2022-01-03, 1400/10/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-01-03, 1400/10/13**

Update count: **0**

#### Registration date

2022-01-03, 1400/10/13

#### Registrant information

##### Name

Fatemeh zahra Bahmani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3725 3372

##### Email address

fzbahmanii@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2021-12-22, 1400/10/01

#### Expected recruitment end date

2022-01-21, 1400/11/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

## Scientific title

comparision of the effect of the carpal lock splint and neoprene splint with anterior (palmar)bar on pain and muscle strength in patients with carpal tunnel syndrome.

## Public title

Comparison of the effect of two therapies (dorsal wrist brace and volar wrist brace) on pain and muscle strength in patients with carpal tunnel syndrome

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients 25 to 65 years old,of both sexes Patients with mild to moderate idiopathic carpal tunnel syndrome lesion EMG findings Fallen or Tinnel positive test Pain,numbness,paresthesia,hypostasis in median nerve disorder

### Exclusion criteria:

Acute trauma and hand fracture Rheumatoid arthritis, diabetes, MS, kidney and thyroid History of carpal tunnel syndrome surgery History of steroid injection in the carpal tunnel in the last 3 months Pregnancy History of orthosis use Neuromuscular diseases

## Age

From **25 years** old to **65 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **26**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Random sequencing was performed using a random number table. messy numbers and without a special pattern provide to patients and we ask them to choose a number from the right, we consider even numbers for the intervention group and odd numbers for the control group,they choose a number if they are even in the intervention group and if they are an individual they are randomly placed in the control group.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

#### Street address

Isfahan, Hezar Jarib Street, Isfahan University of Medical Sciences

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8174673461

#### Approval date

2021-10-02, 1400/07/10

#### Ethics committee reference number

IR.MUI.NUREMA.REC.1400.136

## Health conditions studied

## 1

### Description of health condition studied

carpal tunnel syndrome (CTS)

#### ICD-10 code

G56.0

#### ICD-10 code description

Carpal tunnel syndrome

## Primary outcomes

## 1

### Description

Pain score

### Timepoint

4 weeks

### Method of measurement

VAS Pain video questionnaire

## 2

### Description

Muscle strength

### Timepoint

4 weeks

### Method of measurement

SAEHAN SH5001 dynamometer device

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: Carpal lock splint, for 4 weeks, use at night during sleep and day during activity, tying on the

patient's hand by the researcher (student), construction by the researcher (student), made of hard thermoplastic and soft foam.

**Category**

Treatment - Devices

**2****Description**

Control group: Neoprene splint with anterior bar, for 4 weeks, use at night during sleep and day during activity, tied on the patient's hand by the researcher (student), made by "Sama Teb Pakan" company, its surface is made of neoprene and its bar is made of hard thermoplastic .

**Category**

Treatment - Devices

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Kashani Hospital

**Full name of responsible person**

Fatemeh Zahra Bahmani

**Street address**

hezar jarib street

**City**

Isfahan

**Province**

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**Postal code**

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**Phone**

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**Web page address**

<http://www.mui.ac.ir>

**2****Recruitment center****Name of recruitment center**

Al-Zahra Hospital

**Full name of responsible person**

Fatemeh Zahra Bahmani

**Street address**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr. Tahmoores Tahmasbi

**Street address**

hezar jarib street

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Isfahan

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**Phone**

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**Email**

t\_tahmasbi@yahoo.com

**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**

Fatemeh Zahra Bahmani

**Position**

post graduate student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Orthopedics

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

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**Position**

post graduate student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Orthopedics

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## Person responsible for updating data

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**Name of organization / entity**

Esfahan University of Medical Sciences

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post graduate student

**Latest degree**

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**Phone**

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## Sharing plan

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

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

Numerical data of patients can be published

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

September 2021

**To whom data/document is available**

researchers

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

researchers

**From where data/document is obtainable**

Through the university website, research section

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

Short time after publication

**Comments**