

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

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hezar jarib street

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

Al-Zahra Hospital

Full name of responsible person

Fatemeh Zahra Bahmani

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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

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hezar jarib street

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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

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Full name of responsible person

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Position

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Latest degree

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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