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)
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+98 81 3821 5062
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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
Isfehan

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
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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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Position

Masters student

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Person responsible for updating data

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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