Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effect of Exercise Therapy with Wrist splint on Pain and Function of Patients with Mild Idiopathic Carpal Tunnel Syndrome

Protocol summary

Study aim
Examining the effect of exercise therapy with splint on the improvement of pain and function compared to wrist splinting in patients with mild idiopathic carpal tunnel syndrome

Design
Clinical trial include control group, parallel, double blind, randomized The study has two groups, treatment group (50 subjects) and control group (50 Subjects) Phase 3 clinical trial

Settings and conduct
Severity of the symptoms and hand function will be assessed by Boston carpal tunnel syndrome questionnaire. Then the Grip and Pinch strength, Two-point discrimination, Phalen, Tinel and Compression test will be assessed. Prefabricated splints will be given to both groups. A tendon and nerve gliding exercise program will prescribe to the patients in the treatment group . The exercise therapy last for six weeks. After the treatment, the patients will re-visit and the tests performed at baseline will be repeated for them.

Participants/Inclusion and exclusion criteria
Subjects over 18 years of olds with complaining of symptoms of CTS , and electrophysiological findings of nerve compression will be included. Patients with history of previous treatment with splint or surgery, any trauma on the hands, neck, and shoulders within three months of the study onset, wrist surgery, pregnancy, diabetes, thyroid disorders, and any findings suggesting conditions that interfere with CTS will be excluded.

Intervention groups
A prefabricated splints will be given to both groups and the patients in the treatment group will be prescribed a tendon and nerve gliding exercise program. Patients will be asked to exercise three times a day and hold every position for 5 seconds. The exercise therapy will last for six weeks.

Main outcome variables
Severity of the symptoms will be assessed by BCTQ. The secondary outcome measures such as the grip and pinch strength will be assessed by dynamometer and pinch-meter, respectively.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191222045849N2**
Registration date: **2020-02-08, 1398/11/19**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-08, 1398/11/19**
Update count: **0**

Registration date
2020-02-08, 1398/11/19

Registrant information

Name
Maryam Mirshahi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6634 8500

Email address
m-mirshahi@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-05, 1398/10/15

Expected recruitment end date
2020-03-05, 1398/12/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Exercise Therapy with Wrist splint on Pain and Function of Patients with Mild Idiopathic Carpal Tunnel Syndrome

Public title

The effect of exercise therapy in Carpal Tunnel Syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Symptoms of CTS (pain, paresthesia in the area of hand innervated by the median nerve) and electrophysiological findings of nerve compression (mild CTS)

Exclusion criteria:

Previous treatment with splint or surgery History of any trauma on the hands, neck, and shoulders within three months of the study onset History of wrist surgery Pregnancy History of diabetes, thyroid disorders Any findings suggesting conditions that interfere with CTS (e g, cervical radiculopathy)

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly allocated to receive either splinting or splinting with exercise . A researcher who not involve in the selection and treatment of patients, prepare and sealed opaque envelopes containing the treatment options. After that, every patient randomly will choose one sealed opaque envelope to determine the type of intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

Except sports medicine specialist who educated patients for correct exercising, other researchers, patients, and a person who analysis the data will be blind to the allocated treatments.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Sina Hospital, Imam Khomeini Ave., Hassan Abad Sq., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1136746911

Approval date

2017-02-18, 1395/11/30

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1395.1720

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

Pain and function

Timepoint

Baseline, at two- and six-week intervals after the intervention

Method of measurement

By Boston Carpal Tunnel Questionnaire

Secondary outcomes

1

Description

Grip strength

Timepoint

Baseline, at two- and six-week intervals after the intervention.

Method of measurement

Dynamometer

2

Description
Pinch strength
Timepoint
Baseline, at two- and six-week intervals after the intervention.
Method of measurement
Pinch meter

Intervention groups

1

Description
Intervention group: Wrist splint with tendon and nerve glide exercise, prefabricated splints (wrist splint, Tynor, India) will wear during the night. In tendon glide exercises, fingers are held in five positions of straight, hook, fist, tabletop, and long fist, respectively. The fingers are in full extension in all these positions. At all stages of this exercise, the wrist is in a neutral position. By doing the nerve glide exercises, the median nerve moves through the wrist and the fingers in six different positions. To do this exercise, the elbows are kept supinated with 90 degrees of flexion and shoulder and neck are in the neutral position. In the 1st state, the wrist is in a neutral position, and the fingers and thumb are in the flexion. In the 2nd state, the wrist is in the neutral position, and the fingers and thumb are in the extension. In the 3rd state, the wrist and fingers are in the extension and the thumb is in a neutral position. Then, the wrist, fingers, and thumb are hold in the extension position. In the next step, maintaining the previous position, the forearm is kept supinated. In the final step, a mild extension is applied to the exercising thumb by the opposite hand. All the above steps are performed respectively. Patients will ask to perform all the exercises three times a day, 10 repeats each time, and hold each position for five seconds.
Category
Rehabilitation

2

Description
Control group: Wrist splint (wrist splint, Tynor, India) during at night
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Maryam Mirshahi
Street address
Sina Hospital, Imam Khomeini Ave., Hassan Abad Sq., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8500
Email
m-mirshahi@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammadali Sahraian
Street address
Central Building of Tehran University of Medical Sciences،No. 226, Qods St., Keshavarz Blvd., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1416753955
Phone
+98 21 8889 6694
Email
m-mirshahi@sina.tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Maryam Mirshahi
Position

Sports Medicine Specialist

Latest degree

Specialist

Other areas of specialty/work

Sport Medicine

Street address

Sina Hospital, Imam Khomeini Ave., Hassan Abad Sq., Tehran, Iran

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Contact

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable