Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effects of neurodynamic mobilization and use of orthosis on median nerve stiffness in patients with carpal tunnel syndrome by sonoelastography

Protocol summary

Study aim
Comparison of the effects of neurodynamic mobilization and use of orthosis on median nerve stiffness in patients with carpal tunnel syndrome by sonoelastography

Design
Randomized Clinical trial with stratified randomization, Including two parallel interventional groups, Single blind

Settings and conduct
After screening CTS patients referred to medical centers affiliated to Shiraz University of Medical Sciences and obtaining informed consent, patients would be evaluated and then randomly assigned to two treatment groups and it will be done in the Faculty of Rehabilitation Sciences of Shiraz University of Medical Sciences. The evaluations will be repeated after the end of the treatment. Assessors will not know how patients are assigned to groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having CTS (Carpal Tunnel Syndrome) according to diagnosis criteria of increased sensory or distal motor latency, Having symptoms of CTS for at least one month; Exclusion Criteria: History of surgical interventions in wrist area, History of steroid injection for CTS in the studied hand 6 months before the examination, Joint inflammatory disease, If CTS is associated with pregnancy or diabetes

Intervention groups
One group of patients receive neurodynamic mobilization of median nerve for one week, and the other group receives night wrist hand orthosis for one week.

Main outcome variables
Median nerve stiffness, Symptom severity and function, Nerve conduction velocity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160614028447N8**
Registration date: **2020-09-06, 1399/06/16**
Registration timing: **prospective**

Last update: **2020-09-06, 1399/06/16**
Update count: **0**

Registration date
2020-09-06, 1399/06/16

Registrant information

Name
Amin Kordi Yoosefinejad

Name of organization / entity
Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-20, 1399/08/30

Expected recruitment end date
2021-05-20, 1400/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the effects of neurodynamic mobilization and use of orthosis on median nerve stiffness in patients with carpal tunnel syndrome by sonoelastography

Public title

Comparison of the effects of nerve mobilization and use of orthosis on median nerve stiffness in patients with carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having CTS according to diagnosis criteria of increased sensory or distal motor latency Having symptoms of CTS for at least one month

Exclusion criteria:

History of surgical interventions in wrist area Having received intervention related to CTS for three months before the examination History of steroid injection for CTS in the studied hand 6 months before the examination Joint inflammatory disease If CTS is associated with pregnancy or diabetes Inability to complete questionnaires due to cognitive problems

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified randomization would be performed according to severity of the disease. In each stratum of weak, medium and severe, a separate randomization list is designed, which is based on the permutation block method, and we considered 3 blocks of 4 in each of them. Using random number generator software, random sequences of numbers 0 and 1 are generated and based on that, patients are divided into two treatment groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a one-way blind trial study in which the person performing the sonoelastography evaluation is unaware of the patient's treatment and in order to perform the blinding process, tests and treatments would be done in independent centers and by different people and each of them is unaware of other processes.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Committee on Ethics in Biomedical Research

Street address

Sheikh Abivardi 1, Chamran Blvd., Shiraz

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Shiraz

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Postal code

33669-71947

Approval date

2020-08-19, 1399/05/29

Ethics committee reference number

IR.SUMS.REHAB.REC.1399.029

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

Median nerve stiffness

Timepoint

At the beginning of study (before intervention) and at the end of study (after 1 week of intervention)

Method of measurement

Sonoelastography

Secondary outcomes

1

Description

Symptom severity and function

Timepoint

At the beginning of study (before intervention) and at the end of study (after 1 week of intervention)

Method of measurement

Boston Carpal Tunnel Syndrome Questionnaire

2

Description

Nerve conduction velocity

Timepoint

At the beginning of study (before intervention) and at the end of study (after 1 week of intervention)

Method of measurement

Electrodiagnosis

Intervention groups

1

Description

First intervention group: In neurodynamic technique intervention group, treatment will be done using neurodynamic techniques in median nerve in a supine lying position. Neurodynamic sequence will be as follows: 90 degrees arm abduction, arm external rotation, wrist and hand extension, elbow supination and elbow extension. In this sequence, glide and tension techniques will be done in proximal and distal directions: 1- Glide proximal mobilization (high-amplitude extension movement of the elbow joint), 2- Glide distal mobilization (high-amplitude extension movement of the wrist joint), 3- Tension proximal mobilization (low-amplitude extension movement of the elbow joint at end range), 4- Tension distal mobilization (low-amplitude extension movement of the wrist joint). Neurodynamic protocol includes 3 sets of 60 repetitions of neurodynamic techniques of sliding and tension with 15 seconds rest between each set. Each session lasts for 20 minutes. The intervention would be done once daily for a week.

Category

Rehabilitation

2

Description

Second intervention group: In orthosis intervention group, immobilization would be done by a night wrist-hand orthosis in neutral position and the person is asked to wear it every night for 8 hours and continue it for a week. The orthosis is made specifically for each patient and is made of thermoplastic to be able to keep the wrist in exact neutral position.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Medical centers affiliated to Shiraz University of Medical Sciences

Full name of responsible person

Amin KordiYoosefinejad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Grant name

Vice chancellor of research of Shiraz University of Medical Sciences

Grant code / Reference number

99-01-06-22602

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person
Sahar Khademi

Position
Ph.D. candidate in Physical Therapy

Latest degree
Master

Other areas of specialty/work
Physiotherapy

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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
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
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
All data except personal information would be available.

When the data will become available and for how long
The start of the access period is 6 months after the acceptance of the article.

To whom data/document is available
In addition to the principal researcher and the supervisor of the project, upon request, access to information can be reviewed by the Ethics Committee.

Under which criteria data/document could be used
Researchers can use data for advanced analyses or for meta analysis studies.

From where data/document is obtainable
Dr. Amin KordiYoosefinejad, Shiraz, Chamran Blvd., Sheikh Abivardi 1 ave., School of Rehabilitation Sciences, Mobile: 09171950589, E-mail: yoosefinejad@sums.ac.ir

What processes are involved for a request to access data/document
After 6 months from article acceptance, while announcing a written request to the executor of the project to receive information and a precise explanation about how to use the information, an official letter is also requested to obtain permission from the ethics committee to obtain a license, and if the ethics committee approves, emphasizing the confidentiality of the information, the requested information will be provided to the applicant.

Comments