

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of concurrent myofascial release of the shoulder girdle and hand compared to myofascial release of the hand on functional and electrodiagnostic parameters of patients with mild and moderate carpal tunnel syndrome

Protocol summary

Study aim

Studying the effect of simultaneous shoulder and hand myofascial release compared to hand myofascial release

Design

Individuals will be divided into three groups by simple randomization method, which is done with a dice: 1) simultaneous MFR of the hand and shoulder, 2) MFR of the hand, 3) control group. This study is single-blinded. Each group will include 15 samples and a total of three groups will include 45 samples. To compare the effect of treatment before and after the intervention, ANOVA statistical analysis will be used with SPSS software.

Settings and conduct

Individuals with symptoms of CTS will be referred to the clinic of the Neuromuscular Research Center of Semnan University of Medical Sciences and an initial electrodiagnostic study will be performed. Pain and function will also be assessed with the Visual Pain Scale and the Boston Questionnaire. The evaluator and the therapist are two separate individuals, so this study is single-blind. Myofascial release will be performed in the hand and shoulder girdle area.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 50 years and VAS above 3. Patients with other confounding diagnoses, such as cervical radiculopathy, other mononeuropathies, or polyneuropathies, were excluded from this study. Patients with a positive history of other diseases that may cause secondary CTS or whose disease is associated with secondary CTS, were also excluded from this study if they were pregnant or lactating, or had a history of fracture or surgery.

Intervention groups

Individuals will be randomly divided into three groups using a simple randomization method: 1) simultaneous hand and shoulder myofascial release, 2) hand

myofascial release, and 3) control group

Main outcome variables

Pain; Function; Myofascial Release; Nerve Conduction Velocity; Latency; Amplitude

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250222064806N1**

Registration date: **2025-05-07, 1404/02/17**

Registration timing: **registered_while_recruiting**

Last update: **2025-05-07, 1404/02/17**

Update count: **0**

Registration date

2025-05-07, 1404/02/17

Registrant information

Name

azadeh mokhtari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6608 3104

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-05, 1404/02/15

Expected recruitment end date

2025-07-06, 1404/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of concurrent myofascial release of the shoulder girdle and hand compared to myofascial release of the hand on functional and electrodiagnostic parameters of patients with mild and moderate carpal tunnel syndrome

Public title
Investigating the effect of concurrent myofascial release of the shoulder girdle and hand compared to myofascial release of the hand on functional and electrodiagnostic parameters of patients with mild and moderate carpal tunnel syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age: 18-50 years old Mild & moderate idiopathic CTS VAS above 3
Exclusion criteria:
Cervical radiculopathy Polyneuropathy Diabetes mellitus Hypothyroidism Chronic kidney failure Chronic alcoholism Acromegaly Connective tissue disease Inflammatory diseases Pregnant Breast feeding History of fracture or surgery in the hand More than 20% absence in practice sessions Unwillingness to continue

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, randomization is done by a dice, so that in this 3-group study, numbers 1 and 2 are considered for the first group, numbers 3 and 4 for the second group, and numbers 5 and 6 for the third group.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the evaluator and the therapist are two separate individuals, and the evaluator is blind, so the present study will be single-blind.

Placebo

Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Semnan University of Medical Sciences

Street address
Semnan University of Medical Sciences, Basij Blvd.

City
Semnan

Province
Semnan

Postal code
3519899946

Approval date
2025-02-26, 1403/12/08

Ethics committee reference number
IR.SEMUMS.REC.1403.284

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

Timepoint
After the initial evaluation, individuals in all three groups will undergo 10 treatment sessions, 3 sessions per week for 4 weeks. Four weeks after the last treatment session, the evaluations will be repeated and the results will be reviewed

Method of measurement
Visual Analog Scale(VAS)

2

Description
Function

Timepoint
After the initial evaluation, individuals in all three groups

will undergo 10 treatment sessions, 3 sessions per week for 4 weeks. Four weeks after the last treatment session, the evaluations will be repeated and the results will be reviewed

Method of measurement

Boston CTS questionnaire

3

Description

Myofascial Release

Timepoint

After the initial evaluation, individuals in all three groups will undergo 10 treatment sessions, 3 sessions per week for 4 weeks. Four weeks after the last treatment session, the evaluations will be repeated and the results will be reviewed

Method of measurement

Manual

4

Description

Nerve Conduction Velocity

Timepoint

After the initial evaluation, individuals in all three groups will undergo 10 treatment sessions, 3 sessions per week for 4 weeks. Four weeks after the last treatment session, the evaluations will be repeated and the results will be reviewed

Method of measurement

Electrodiagnostic studies with an EMG device

5

Description

Latency

Timepoint

After the initial evaluation, individuals in all three groups will undergo 10 treatment sessions, 3 sessions per week for 4 weeks. Four weeks after the last treatment session, the evaluations will be repeated and the results will be reviewed

Method of measurement

Electrodiagnostic studies with an EMG device

6

Description

Amplitude

Timepoint

After the initial evaluation, individuals in all three groups will undergo 10 treatment sessions, 3 sessions per week for 4 weeks. Four weeks after the last treatment session, the evaluations will be repeated and the results will be reviewed

Method of measurement

Electrodiagnostic studies with an EMG device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: concurrent myofascial release of the shoulder girdle and hand Myofascial release of the shoulder girdle area is performed on the upper trapezius, pectoralis major, supraspinatus, and subscapularis. The same hand release will be performed on the carpal ligament area of the wrist. The release will last 90 to 120 seconds, followed by a ten-second rest, and this technique will be repeated 5 times per session. The group will undergo 10 treatment sessions, 3 sessions per week for 4 weeks.

Category

Treatment - Other

2

Description

Intervention group: Intervention group2: Hand Myofascial Release Myofascial release will be performed on the carpal ligament area of the wrist. The release will last for 90 to 120 seconds, followed by a ten-second rest, and this technique will be repeated 5 times per session. The group will undergo 10 treatment sessions, 3 sessions per week for 4 weeks.

Category

Treatment - Other

3

Description

Control group: In the control group, only routine physiotherapy is performed. Routine physiotherapy is performed in the form of applying a high-frequency TENS current for fifteen minutes with a frequency of 100 HZ and a diurnance of 100 with an amplitude of 15 mA and 5 minutes with a frequency of 1 HZ and a diurnance of 200 with an amplitude of 5 mA in a two-channel manner on the wrist and palm area. Then, pulsed ultrasound current with a frequency of 1 MHz and an intensity of 0.8 watts/square centimeter will be used for 3 minutes on the carpal ligament area of the wrist. After that, infrared will be used for 15 minutes at a distance of 50 cm. The group will undergo 10 treatment sessions, 3 sessions per week for 4 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Research Center, Semnan University of Medical Sciences

Full name of responsible person

Azadeh Mokhtari

Street address

Neuromuscular Rehabilitation Research Center,
Tabatabaei Clinic, Qods Boulevard

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9837535196

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Email

azadehmokhtari27@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Abbasali Vafaei

Street address

Headquarters of Semnan University of Medical
Sciences, Basij Boulevard

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3514799442

Phone

+98 23 3344 1022

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Azadeh Mokhtari

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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+98 23 3365 4180

Email

azadehmokhtari27@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Azadeh Mokhtari

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Student

Latest degree

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Other areas of specialty/work

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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

"There is no further information."

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

All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

"Access period begins 6 months after results are published."

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

There are no other conditions.

From where data/document is obtainable

azadehmokhtari27@gmail.com

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

Two weeks after submitting the request, an email will be sent to the applicant and the individual's academic identity will be verified.

Comments