Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+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 radiculopathypoly 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 terapezius, 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
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3514799442

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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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Position
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Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

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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