

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of dry needling on painful myofascial points of scapular and shoulder muscles on pain and function of patients with carpal tunnel syndrome

Protocol summary

Study aim

The evaluation of the effects of adding dry needling of scapular and shoulder muscles myofascial trigger points to routine physiotherapy on pain and function of patients with CTS

Design

This clinical trial has a control group, with parallel groups, double-blinded and randomized by block randomization method with block size 4. The sample size is 20 persons in each group.

Settings and conduct

Patients (n: 40) referred to medical centers of SUMS who suffer from carpal tunnel syndrome, enter the study according to the inclusion and exclusion criteria and after signing the informed consent. They are randomly assigned to intervention group (routine physiotherapy with dry needling) and control group (routine physiotherapy). Treatment will be done by a physiotherapist. assessments will be performed by another physiotherapist and statistical analysis by a statistician who are unaware of group assignment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with mild to moderate carpal tunnel syndrome; age between 30-60 years; pain and paresthesia in the hand; positive phalen's test and tinell's sign; myofascial painful points around the scapula and shoulder. Exclusion criteria: cervical disc herniation; cervical radiculopathy; cervical vertebrae degeneration; upper limb fractures; diabetes and rheumatoid arthritis.

Intervention groups

The control group undergoes routine physiotherapy including ultrasound, TENS, hot pack and nerve mobilization techniques in 10 sessions for 2 weeks on the wrist area. The intervention group undergoes dry needling in the muscles around the shoulder and scapula in addition to the interventions of the control group.

Main outcome variables

Pain; Grip power; Function; Two point discrimination

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220530055032N1**

Registration date: **2022-07-27, 1401/05/05**

Registration timing: **prospective**

Last update: **2022-07-27, 1401/05/05**

Update count: **0**

Registration date

2022-07-27, 1401/05/05

Registrant information

Name

Sedighe Rezaeyan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3631 7233

Email address

sedigherezaeyan73@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-06, 1401/05/15

Expected recruitment end date

2023-02-04, 1401/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of dry needling on painful myofascial points of scapular and shoulder muscles on pain and function of patients with carpal tunnel syndrome

Public title

Evaluation of the effect of dry needling of scapular and shoulder muscles painful points on pain and function of patients with carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with mild to moderate carpal tunnel syndrome
Aged between 30 and 60 years
Pain and paresthesia in hand (especially thumb, index and middle fingers)
Having symptoms for more than one month
Positive Phalen's test
Positive Tinel's test
Painful myofascial points at least in two muscles around scapula (Upper Trapezius, Supraspinatus, Infraspinatus, Subscapularis, Teres minor and major) and at least in one muscle around shoulder (Biceps and Deltoid)
Normal BMI to overweight

Exclusion criteria:

Cervical disc protrusion
Cervical radiculopathy
Cervical vertebral degeneration
Double crush syndrome
Upper limb fracture
Sensory or motor defects of the ulnar or radial nerves
History of wrist or cervical spine severe injury
Previous wrist, upper limb or cervical vertebrae surgeries
History of steroid injection into the wrist
History of systemic disease causing carpal tunnel syndrome such as diabetes, rheumatoid arthritis and fibromyalgia
Pregnancy
Thenar muscles atrophy
Use of blood thinner drugs
Tumor
Epilepsy

Age

From **30 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly divided into two equal groups of routine physical therapy and routine physical therapy plus dry needling via Block randomization method, with a block size of 4 by using of random allocation software.

Blinding (investigator's opinion)

Double blinded

Blinding description

The treatment will be performed by a physiotherapist

and the variables will be measured by another physiotherapist who is unaware of the allocated groups, and the data will be analyzed by a statistician who is unaware of the group assignments.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Shiraz University of Medical Sciences

Street address

School of Rehabilitation, Abiverdi 1 St., Chamran Blvd., Shiraz, Fars, Iran

City

Shiraz

Province

Fars

Postal code

7194733669

Approval date

2022-05-11, 1401/02/21

Ethics committee reference number

IR.SUMS.REHAB.REC.1401.006

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

Before treatment, after the last treatment session, 1 month after the last treatment sessions

Method of measurement

Visual analogue scale

2**Description**

Grip power

Timepoint

Before treatment, after the last treatment session, 1 month after the last treatment sessions

Method of measurement

Hand-held dynamometer

3

Description

Functional disability

Timepoint

Before treatment, after the last treatment session, 1 month after the last treatment sessions

Method of measurement

DASH questionnaire

4

Description

Severity and functional ability

Timepoint

Before treatment, after the last treatment session, 1 month after the last treatment sessions

Method of measurement

Boston questioner

5

Description

Two point discrimination

Timepoint

Before treatment, after the last treatment session, 1 month after the last treatment sessions

Method of measurement

Two point discriminator

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients will receive 10 sessions of routine physical therapy at the wrist area: therapeutic continuous ultrasound (for 5 min with 3.0 MHz applicator, ERA = 5 cm², intensity= 1.5 W/cm²); Burst TENS on median nerve (frequency 100Hz, pulse width 80 ms, electrode size 4* 6 for 20 min); hot pack on wrist area; median nerve mobilization technique; Dry needling technique in the muscles around the scapula and shoulder.

Category

Rehabilitation

2

Description

Control group: patients will receive 10 sessions of routine physical therapy at the wrist area: therapeutic

continuous ultrasound (for 5 min with 3.0 MHz applicator, ERA = 5 cm², intensity= 1.5 W/cm²); Burst TENS on median nerve (frequency 100Hz, pulse width 80 ms, electrode size 4* 6 for 20 min); hot pack on wrist area; median nerve mobilization technique.

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

Dr Samaneh Ebrahimi

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School of Rehabilitation, Abiverdi 1 St., Chamran Blvd., Shiraz, Fars, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Mahtab Memarpour

Street address

Vice Chancellor for Research and Technology, Zand St. Shiraz, Fars The central building of Shiraz University of Medical Sciences, seventh floor

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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

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

Sedighe Rezaeyan

Position

Master of Science Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Latest degree

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Other areas of specialty/work

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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

No - There is not 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

After coordination with the Research Ethics Committee for approval of the ethics committee, participants data file will be provided in complete secrecy and for research purposes only.

When the data will become available and for how long

6-12 month after acceptance of the article by the journal.

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

Preferably it is only used for the subject of my research, but if research is to be done in order to use the statistical population, the main project executor and the student's main collaborator will make a decision with the permission of the ethics committee.

From where data/document is obtainable

Executors of the project can first be referred to through Dr. Zahra Rojhani Shirazi (09171127108), and the main colleague and student collaborator Ms Fatemeh Panahi

(09183571646).

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

6 months after article publication, referring the request to the executor of the project, an official letter from the ethics committee will be commented on in order 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