Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 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 tinel'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
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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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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

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
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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
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