Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Investigating the effect of rotator cuff trigger points dry needling on the stability and function of the upper limb in people with shoulder pain

Protocol summary

Study aim
The aim of this study was to investigate the effect of rotator cuff dry needling on the stability and function of the upper limb in people with shoulder pain.

Design
A clinical trial with controlled group , single blind , randomized

Settings and conduct
In this clinical trial study, 40 patients with shoulder pain who referred to clinics affiliated to Shiraz School of Rehabilitation Sciences will be divided into two groups using a random method: the first group of dry needling and The second group receive sham dry needling.

Participants/Inclusion and exclusion criteria
This study are perform in people with shoulder pain who have had at least 3 months of pain and they have at least one active trigger point in two the muscle is made up of four rotator cuff muscles. And if they have special injury in the shoulder and neck joints or prohibited from using dry needling, they will be excluded from the study.

Intervention groups
Dry needling Group: People with shoulder pain who receive three sessions of dry needling in one week of treatment (every other day), in the trigger points of the rotator cuff muscles (supraspinatus, infraspinatus, subscapularis and teres minor). Control group: people with shoulder pain who receive the sham dry needling in the said muscles, in three sessions; They receive the same as the treatment group. Samples recruited from rehabilitation clinics of Shiraz University of Medical Sciences.

Main outcome variables
Shoulder stability and upper extremity function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190909044734N4**
Registration date: **2023-08-20, 1402/05/29**
Registration timing: **prospective**

Last update: **2023-08-20, 1402/05/29**
Update count: **0**

Registration date
2023-08-20, 1402/05/29

Registrant information

Name
Leila Abbasi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-06, 1402/06/15

Expected recruitment end date
2023-10-07, 1402/07/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of rotator cuff trigger points dry needling on the stability and function of the upper limb in people with shoulder pain

Public title

Investigating the effect of dry needling of the rotator cuff muscles on the stability and function of the upper limb in people with shoulder pain.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Presence of shoulder pain for at least three months Existence of trigger points with three characteristics: 1. Existence of a palpable knot in the skeletal muscle band.2. Existence of excessive points Irritable in taut band 3. Patients who report local or referred pain after mechanical stimulation of trigger points. (with the difference that latent trigger points become painful only after mechanical stimulation and active points even without stimulation. It is a mechanism that causes myofascial pain) The presence of at least one trigger point in two of the four rotator cuff muscles

Exclusion criteria:

History of shoulder and neck surgery Instability of the glenohumeral joint and serious diseases related to the joint of cervical vertebrae, ang glenohumeral joint History of corticosteroid injections or local anesthetics in the past year Symptoms indicating systemic disorders History of any physiotherapy in the last 3 months History of diagnosis or medical reports about the presence of myopathy and neuropathy Cognitive problems Patients with any limitations in dry needling treatment (fear of needles, patient dissatisfaction, lymphoedema, Acute and emergency conditions, patients with coagulation problems, immune system disorders, vascular problems, diabetes, epilepsy, allergy to metals, patients with mental disorders, use of anticoagulants) Use of anti-platelet, anti-coagulant, anti-pain and anti-inflammatory drugs in the last three months Cardiovascular, rheumatoid, and neurological problems History of rotator cuff tears

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Using of randomization software, 40 numbers are considered for each case and the software defines 10 blocks of 4, from 4 to 2 people in the dry needling group and 2 people in sham dry needling. They are dried and thus 40 people are completed.

Blinding (investigator's opinion)

Single blinded

Blinding description

The person who will evaluate the patients and analyze the data is completely unaware of the details of the patient grouping and the treatments performed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research, Shiraz Faculty of Rehabilitation Sciences

Street address

Abiverdi Street 1, Chamran Blvd

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1733-71345

Approval date

2023-07-26, 1402/05/04

Ethics committee reference number

IR.SUMS.REHAB.REC.1402.009

Health conditions studied

1

Description of health condition studied

Shoulder pain

ICD-10 code

M25.51

ICD-10 code description

Pain in shoulder

Primary outcomes

1

Description

Stability of shoulder

Timepoint

Before the intervention, after the end of the treatment and one week after the end of the treatment as a follow-up

Method of measurement

Closed Kinetic Chain Upper Extremity Stability Test

2

Description

Upper extremity function

Timepoint

Before the intervention, after the end of the treatment and one week after the end of the treatment as a follow-up

Method of measurement

Quick Disabilities of Arm, Shoulder & Hand questionnaire

3

Description

Grip strenght

Timepoint

Before the intervention, after the end of the treatment and one week after the end of the treatment as a follow-up

Method of measurement

Dynamometer device

4

Description

Shoulder pain

Timepoint

Before the intervention, after the end of the treatment and one week after the end of the treatment as a follow-up

Method of measurement

Visual Analogue Scale

5

Description

The strength of internal and external rotators of the shoulder joint

Timepoint

Before the intervention, after the end of the treatment and one week after the end of the treatment as a follow-up

Method of measurement

Dynamometer device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: dry needling: people with shoulder pain who received 3 dry needling sessions per week according to the routine of the control group3 times during a week of treatment (one day in between), in the trigger points of the rotator cuff muscles (supraspinatus, infraspinatus, subscapularis and teres minor).

Category

Rehabilitation

2

Description

Control group: sham dry needling group: people with shoulder pain who received dry needling in the rotator cuff muscles (supraspinatus, infraspinatus, subscapularis and teres minor) and practically the needle does not enter the skin.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz School of Rehabilitation

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
Leila Abbasi

Position
Assistant Professor

Latest degree
Ph.D.

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
No more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available