

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3627 1551

###### Email address

leabbasi@sums.ac.ir

##### 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

##### **City**

Shiraz

##### **Province**

Fars

##### **Postal code**

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 strength

**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 group 3 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**

Leila Abbasi

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Younes Ghasemi

**Street address**

Research Deputy, Central building of Shiraz University of Medical Sciences, Opposite Palestine St, Zand St.

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ghasemiy@sums.ac.ir

**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

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**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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Leila Abbasi

**Position**

استادیار دانشگاه علوم پزشکی شیراز

**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