

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### The effectiveness of acupuncture on pain and function of the patients who have shoulder pain

#### Protocol summary

##### Study aim

Effectiveness of acupuncture on pain and function of the patients who have shoulder pain

##### Design

A double blinded Randomized Control Trial (RCT)

##### Settings and conduct

Patients with shoulder pain more than 6 weeks are referred to the sports medicine clinic of Rasoul-e-Akram Hospital, they are examined by the sports medical specialist and if tendinopathy or incomplete tear of their Rotator Cuff would be diagnosed by physical exams & confirmed by MRI findings, The therapist who performs the assessments as well as the analyzer will not know the treatment information. Outcomes are compared before and after treatment.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Shoulder pain more than six weeks  
Tendinopathy or partial tear of rotator cuff tendons  
Exclusion criteria Total tear of rotator cuff The history of shoulder surgery

##### Intervention groups

Intervention group 1: Acupuncture; Intervention group 2: Sham acupuncture group; Control group 3: Exercise therapy

##### Main outcome variables

Patients' pain and function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100718004409N13**  
Registration date: **2020-04-24, 1399/02/05**  
Registration timing: **registered\_while\_recruiting**

Last update: **2020-04-24, 1399/02/05**

Update count: **0**

##### Registration date

2020-04-24, 1399/02/05

##### Registrant information

###### Name

Parisa Nejati

###### Name of organization / entity

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4480 0361

###### Email address

parisanejati@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-19, 1399/01/31

##### Expected recruitment end date

2020-10-22, 1399/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effectiveness of acupuncture on pain and function of the patients who have shoulder pain

##### Public title

The effectiveness of acupuncture on the patients who have shoulder pain

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Shoulder pain lasted more than 6 weeks At least 3

positive specific shoulder tests MRI findings implying tendinopathy or partial tear of rotator cuff

**Exclusion criteria:**

The presence of sensory or motor disturbances in the upper extremity Evidence from other pathologies that can lead to shoulder pain. For example, the presence of calcified tendonitis or adhesive capsulitis and ... History of shoulder surgery in the last 6 months The presence of inflammatory rhomatologic diseases such as rheumatoid arthritis, fibromyalgia, poly mialia rheumatica and ... Complete rupture of rotator cuff tendons based on MRI findings History of corticosteroid, analgesic or hyaluronic acid injection in the shoulder joint over the past 3 months History of exercise therapy and physiotherapy modalities over the past 6 weeks Use of other therapies during the intervention period Patients request for discontinuing the treatment Contraindications for performing MRI

**Age**

From **40 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **72**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The included patients will be randomized in a simple randomization method. The random number tables found in the most statistical text books will be used for the random numbers. The numbers between 0-23 are considered for the first group, 24-47 for the second group and 48 -73for the third group. The 3 groups are 1- Acupuncture, 2- Sham & 3- Exercise therapy. concealment is performed in sequentially numbered, sealed & opaque envelopes, and will be kept by the department secretary.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

After randomization the patients of the each group will be introduced to the researcher 2 by the researcher 1 for evaluation of the outcomes. The researcher 2 only evaluates the outcomes and records the findings without being informed of the intervention and its effects. The analyzer receives the data at the end of the study and is not informed of the intervention groups at all.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethic committee of Iran university of medical sciences

**Street address**

Iran University of Medical Sciences, Near the Milad Tower,Hemmat highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2020-01-21, 1398/11/01

**Ethics committee reference number**

IR.IUMS.FMD.REC.1399.013

**Health conditions studied**

**1**

**Description of health condition studied**

rotator cuff tendinopathy, partial tear of rotator cuff

**ICD-10 code**

M75.1

**ICD-10 code description**

Rotator cuff tear or rupture, not specified as traumatic

**2**

**Description of health condition studied**

Shoulder impingement

**ICD-10 code**

M75.40

**ICD-10 code description**

Impingement syndrome of unspecified shoulder

**Primary outcomes**

**1**

**Description**

pain amount

**Timepoint**

Before intervention, 1 ,3 ,6 months after intervention

**Method of measurement**

Visual Analog Scale

**2**

**Description**

Function of the patients

**Timepoint**

Before intervention, 1 ,3 ,6 months after itervention

## Method of measurement

Western Ontario Rotator cuff Index(WORC)questionnaires  
,The Disabilities of the Arm, Shoulder, and Hand  
Outcome Measure (DASH) questionnaires

## Secondary outcomes

### 1

#### Description

Shoulder range of motion

#### Timepoint

Before the intervention, 1,3,6 months after intervention

#### Method of measurement

Goniometry

### 2

#### Description

Rotator cuff strength

#### Timepoint

Before the intervention, 1,3,6 months after intervention

#### Method of measurement

Muscle Manual Test

## Intervention groups

### 1

#### Description

Intervention group1: Accupuncture group are needed in accupuncture points in shoulder , 20 millimeter deep inside the skin ,3 sessions a week for 10 session .each session is 10 minutes

#### Category

Treatment - Devices

### 2

#### Description

Intervention group2: Sham accupuncture group are needed in accupuncture points in shoulder ,With distance 20 centimeter of main points ,10 millimeter deep inside the skin ,3 sessions a week for 10 session .each session is 10 minutes

#### Category

Treatment - Devices

### 3

#### Description

Control group: In exercise group , stretching exercise for shoulder ,isometric exercises and passive range of motion each session 3 set 10 repetition daily and strengthening exercises and progressive strengthening exercises ,each session 3 set 10 repetition daily for 6 weeks.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Iran university of medical sciences, Rasool hospital,sports medicine clinic

##### Full name of responsible person

Parisa Nejati

##### Street address

Sattarkhan, Niayesh st.

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

##### Phone

+98 21 6435 2446

##### Email

parisanejati2@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Abbas Motevalian

##### Street address

Iran University of Medical Sciences, Near the Milad Tower, Hemmat Highway

##### City

Tehran

##### Province

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##### Postal code

1449614535

##### Phone

+98 21 86701

##### Email

amotevalian@yahoo.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Iran 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

1445613131

## Person responsible for general inquiries

### Phone

+98 21 6651 5001

### Email

parisanejati@iums.ac.ir

### Contact

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Parisa Nejati

#### Position

Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Sport Medicine

#### Street address

Rasool hospital, Niayesh st.

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Parisa Nejati

#### Position

Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

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#### Phone

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#### Email

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Parisa Nejati

#### Position

Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Sport Medicine

#### Street address

Rasool hospital, Niayesh street, Sattarkhan street

#### City

Tehran

#### Province

Tehran

#### Postal code

## 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

Unawareness of this item

### 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