

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 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

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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

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Sattarkhan, Niayesh st.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Abbas Motevalian

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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

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

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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

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Position

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Latest degree

Specialist

Other areas of specialty/work

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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