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
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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 secretory.

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 needled 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 needled 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 , streching 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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Sponsors / Funding sources

1

Sponsor
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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

Person responsible for general 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
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Person responsible for updating data

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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
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