Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of acupuncture effectiveness in reducing pain and improving shoulder function in patients with rotator cuff tendinopathy

Protocol summary

Study aim
Investigation of acupuncture effectiveness in reducing pain and improving shoulder function in patients with rotator cuff tendinopathy

Design
Clinical trials with a control group, single-blind, randomized. Patients are randomly divided into two groups using SPSS software.

Settings and conduct
This study will be performed on all patients referred to the Physical Medicine and Rehabilitation Clinics of Isfahan University of Medical Sciences in 2019, whose diagnosis of rotator cuff tendinopathy has been confirmed. Sampling will be done based on inclusion and exclusion criteria and for each treatment group, 18 samples and a total of 36 samples will be considered. The statistical analyst of this study will be blinded (single-blind).

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with unilateral rotator cuff tendinopathy, the signature of the consent form and have previous normal radiography of the shoulder. Exclusion criteria: previous surgery of the injured shoulder, luxation or fracture near the shoulder, direct or indirect severe injuries following traction, neurological injuries or illnesses with musculoskeletal disorders, vascular disorders in the lower extremities.

Intervention groups
Control group: In this group, the drug treatment will be one tablet of meloxicam 15 mg with food once a day for two weeks and exercise therapy three times a week for three weeks. Intervention group: In this group, the drug treatment will be one tablet of meloxicam 15 mg with food once a day for two weeks and exercise therapy three times a week for three weeks and acupuncture treatment three sessions per week over three weeks.

Main outcome variables
Clinical parameters include: pain, shoulder joint function, and Painful range of shoulder joint before, immediately and three months after the intervention.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200514047443N1**
Registration date: **2020-10-08, 1399/07/17**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-08, 1399/07/17**
Update count: **0**

Registration date
2020-10-08, 1399/07/17

Registrant information

Name
Faranak Seydi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 84 3362 2690

Email address
faranakseydi1992@resident.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-28, 1399/03/08

Expected recruitment end date
2021-03-20, 1399/12/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Investigation of acupuncture effectiveness in reducing pain and improving shoulder function in patients with rotator cuff tendinopathy

Public title
Acupuncture effectiveness in reducing pain and improving shoulder function in patients with rotator cuff tendinopathy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with unilateral rotator cuff tendinopathy Signature of consent form Have previous normal radiography of the shoulder

Exclusion criteria:
previous surgery of the injured shoulder luxation or fracture near the shoulder Direct or indirect severe injuries following traction Coagulation disorders neurological injuries or illnesses with musculoskeletal disorders Vascular disorders in the lower extremities lymphedema Kidney disease (creatinine greater than 1.5) Drug consumption History of cancer Inability to communicate and cognitive impairment

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples are selected by available and non-probabilistic methods and from among them, patients who meet the inclusion criteria will be selected. Then patients will be divided into two groups of control and intervention by simple random method (code will be assigned to each sample) and using SPSS statistical software. In this study, concealment will be performed by using the method of using sequentially numbered, sealed, opaque envelopes.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, only the statistical analyst will be unaware of the groups studied.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences

Street address
Hezar Jerib Ave

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2020-02-29, 1398/12/10

Ethics committee reference number
IR.MUI.MED.REC.1398.621

Health conditions studied

1

Description of health condition studied
Rotator cuff tendinopathy

ICD-10 code
M75.4

ICD-10 code description
Impingement syndrome of shoulder

Primary outcomes

1

Description
Pain

Timepoint
Before, immediately and three months after the intervention

Method of measurement
with Visual analogue scale (VAS)

2

Description
Shoulder joint function

Timepoint
Before, immediately and three months after the intervention

Method of measurement
Disabilities of the Arm, Shoulder, and Hand outcome Measure (DASH)

3

Description

Painful range of shoulder joint

Timepoint

Before, immediately and three months after the intervention

Method of measurement

with Goniometer

Secondary outcomes

empty

Intervention groups

1

Description

Control group: In this group, the drug treatment will be one tablet of meloxicam 15 mg with food once a day for two weeks and exercise therapy three times a week for three weeks.

Category

Treatment - Other

2

Description

Intervention group: In this group, the drug treatment will be one tablet of meloxicam 15 mg with food once a day for two weeks and exercise therapy three times a week for three weeks and acupuncture treatment three sessions per week over three weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Physical Medicine and Rehabilitation Clinics of Isfahan University of Medical Sciences

Full name of responsible person

Faranak Seydi

Street address

Hezar Jerib Ave

City

Isfahan

Province

Isfehan

Postal code

8174675731

Phone

+98 31 3670 0666

Email

Faranakseydi71@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Parisa Taheri

Street address

Hezar Jerib Ave

City

Isfahan

Province

Isfehan

Postal code

8174675731

Phone

+98 31 3670 0666

Email

prs_taheri@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Faranak Seydi

Position

Post Graduate

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

Hezar Jerib Ave

City

Isfahan

Province

Isfehan

Postal code

8174675731

Phone

+98 31 3670 0666

Email

Faranakseydi71@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Faranak seydi

Position
Post Graduate

Latest degree
Medical doctor

Other areas of specialty/work
Physical Medicine

Street address
Hezar Jerib Ave

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3670 0666

Email
Faranakseydi71@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Faranak seydi

Position
Post Graduate

Latest degree
Medical doctor

Other areas of specialty/work
Physical Medicine

Street address
Hezar Jerib Ave

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3670 0666

Email
Faranakseydi71@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available