

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison the effect of acupuncture treatment with local methylprednisolone acetate injection in De Quervain's tenosynovitis

#### Protocol summary

##### Summary

The aim of this study is to determine the efficacy of acupuncture in comparison with local methylprednisolone acetate injection in relief of pain and improvement of function in the patients suffered from De Quervain's tenosynovitis. Study Design: Randomized clinical trial. Group of study: The patients who refer to Physical medicine and rehabilitation clinics of Shiraz University of Medical Sciences with clinical diagnosis of De Quervain's tenosynovitis. Inclusion criteria: The patients with clinical diagnosis of De Quervain's tenosynovitis including pain and swelling around styloid process of radius and positive Finkelstein test who have symptoms more than 4 weeks. Exclusion criteria: The patients with acute symptom less than 4 weeks; history of direct trauma or fracture of wrist; previous history of local injection or surgery around styloid process of radius; uncontrolled concomitant disease such as diabetes mellitus or coagulopathy; abnormal findings in blood tests and radiography of wrist. Sample size: 30 people. Interventions: The local methylprednisolone acetate injection is performed for 1 session in control study group and acupuncture therapy is done for 5 sessions in case study group. Thumb spica splint is prescribed for both groups. Time of intervention: Intervention is performed after diagnosis of De Quervain's tenosynovitis. Outcome of study: Function of patients is evaluated based on Quick- Disabilities of the Arm, Shoulder and Hand (Q-DASH) score and pain is determined with Visual Analogue Scale (VAS) score.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013012012194N1**

Registration date: **2013-02-13, 1391/11/25**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-02-13, 1391/11/25

##### Registrant information

###### Name

Maryam Sadat Fakhri

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1648 6992

###### Email address

fakhri@sums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

##### Expected recruitment start date

2013-01-07, 1391/10/18

##### Expected recruitment end date

2013-03-20, 1391/12/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effect of acupuncture treatment with local methylprednisolone acetate injection in De Quervain's tenosynovitis

##### Public title

Comparison the effect of acupuncture in treatment of De Quervain's disease with steroid injection

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: The patients with clinical diagnosis of De Quervain's tenosynovitis including pain and swelling around styloid process of radius and positive Finkelstein test who have symptoms more than 4 weeks. Exclusion criteria: The patients with acute symptom less than 4 weeks; history of direct trauma or fracture of wrist; previous history of local injection or surgery around styloid process of radius; uncontrolled concomitant disease such as diabetes mellitus or coagulopathy; abnormal findings in blood tests and radiography of wrist.

## Age

No age limit

## Gender

Both

## Phase

2

## Groups that have been masked

No information

## Sample size

Target sample size: 30

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

##### Street address

Zand street

##### City

Shiraz

##### Postal code

7134814336

##### Approval date

2013-01-06, 1391/10/17

##### Ethics committee reference number

CT-P-91-3121

## Health conditions studied

### 1

#### Description of health condition studied

De Quervain's tenosynovitis

#### ICD-10 code

M65.4

#### ICD-10 code description

Radial styloid tenosynovitis [de Quervain]

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Prior to the intervention, 2 weeks and 6 weeks after the end of intervention

#### Method of measurement

Visual Analogue Scale (VAS) score

### 2

#### Description

function

#### Timepoint

Prior to the intervention, 2 weeks and 6 weeks after the end of intervention

#### Method of measurement

Quick- Disabilities of the Arm, Shoulder and Hand (Q-DASH) score

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group (Acupuncture): Sterile needles are inserted perpendicularly into LI-5, LU-7, LU-9 and also ashi points (points with maximal tenderness) to the depth of 0.5 cun. These points are selected based on the meridians contributing to the affected area of wrist. Acupuncture treatment consists of 5 sessions of 30 minutes duration that is administered within 1 week. (1 cun: The breadth of the patient's thumb)

#### Category

Treatment - Other

### 2

#### Description

Control group (injection): To inject the sheath around the abductor pollicis longus and extensor pollicis brevis tendons, the insulin needle is inserted 1 cm proximal to the radial styloid process at the angle of 45 degree from the skin and parallel to the direction of the tendons. If resistance is so high, the needle is slightly pulled back and then a mixture of 0.5 ml of (40 mg) methylprednisolone acetate and 0.5 ml of 2% lidocaine is

injected. The injection is performed for one session.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Physical medicine and rehabilitation clinic, Shahid Faghihi Hospital

**Full name of responsible person**

Maryam Sadat Fakheri (Resident of physical medicine and Rehabilitation)

**Street address**

Zand street

**City**

Shiraz

**2**

**Recruitment center**

**Name of recruitment center**

Physical medicine and rehabilitation clinic, Shahid Chamran Hospital

**Full name of responsible person**

Maryam Sadat Fakheri (Resident of Physical Medicine and Rehabilitation)

**Street address**

Shahid Chamran street

**City**

Shiraz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Shiraz University of Medical Sciences

**Full name of responsible person**

Hatam Gholamreza, Vice chancellor for Research of Shiraz University of medical sciences

**Street address**

Zand street, Central Building of Shiraz University of Medical Sciences

**City**

Shiraz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research, Shiraz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Shiraz university of medical sciences

**Full name of responsible person**

Dr. Alireza Ashraf

**Position**

Associate Professor of physical medicine and rehabilitation

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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**Position**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*