Clinical Trial Protocol
Iranian Registry of Clinical Trials
03 Sep 2020

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
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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
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2
Recruitment center
Name of recruitment center
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Full name of responsible person
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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
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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
Vice chancellor for research, Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty

Person responsible for general inquiries

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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