

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A comparison between thumb spica cast and Corticosteroid injection vs. Corticosteroid injection in pain and functional outcomes of patients with De Quervain disease.

Protocol summary

Summary

(1) Objectives: A comparison between thumb spica cast and Corticosteroid injection vs. Corticosteroid injection in treatment of patients with de Quervain disease. (2) Design: Randomized clinical trial. (3) Setting and conduct: Group A will receive thumb spica cast for 3 weeks and "Methyl-prednisolon acetate" 40 milligrams plus 1 c.c of "lidocaine" 2% (60 mg) will be injected in maximal point tenderness, In group B "Methyl-prednisolon acetate" 40 milligrams plus 1 c.c of "lidocaine" 2% (60 mg) will be injected. VAS and Quick DASH questionnaires will be completed again after 3 weeks. Also, each patient will fill demographic questionnaire including age, gender, first refer time, involved hand, dominant hand and characteristic of disease. (4) Inclusion criteria: All patients should have 4 criteria: Pain at the radial wrist; Tenderness at the first dorsal extensor compartment; A positive Finkelstein test; VAS score more than 6. Exclusion criteria: Pregnancy and history of rheumatoid arthritis. (5) Intervention: Intervention group: Thumb spica cast and Corticosteroid injection, Control group: Corticosteroid injection. (6) Main outcome measures: primary outcome is Lack of the 4 criteria: Pain at the radial wrist; Tenderness at the first dorsal extensor compartment; A positive Finkelstein test; and VAS score more than 6 will be considered as successful treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109177274N2**
Registration date: **2012-02-01, 1390/11/12**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-02-01, 1390/11/12

Registrant information

Name

Mohsen Mardani Kivi

Name of organization / entity

Guilan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Guilan University of Medical Sciences

Expected recruitment start date

2011-12-06, 1390/09/15

Expected recruitment end date

2012-03-05, 1390/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between thumb spica cast and Corticosteroid injection vs. Corticosteroid injection in pain and functional outcomes of patients with De Quervain disease.

Public title

A comparison between casting and Corton injection vs.

Corton injection in treatment of patients with wrist tendinitis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients should have 4 criteria: Pain at the radial wrist; Tenderness at the first dorsal extensor compartment; A positive Finkelstein test; and VAS score more than 6. Exclusion criteria: Pregnancy; and history of rheumatoid arthritis.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 60

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, Guilan University of Medical Sciences

Street address

Vice chancellor for research, Guilan University of Medical Sciences, Namjou avenue Rasht Guilan Iran, Islamic Republic Of

City

Rasht

Postal code

Approval date

2011-12-01, 1390/09/10

Ethics committee reference number

1901055802

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

successful treatment that explained as lack of the three criteria: 1) Pain at the radial wrist. 2) Tenderness at the first dorsal extensor compartment. 3) A positive Finkelstein test.

Timepoint

refer time and 3 weeks after treatment

Method of measurement

History and physical examination

Secondary outcomes

1

Description

pain severity

Timepoint

before treatment and 3 weeks after treatment

Method of measurement

value-added service (VAS) score

2

Description

disability of elbow score

Timepoint

before treatment and 3 weeks after treatment

Method of measurement

The Disabilities of the Arm, Shoulder and Hand Score(QuickDash)

Intervention groups

1

Description

Intervention Group: All patients in this group will be provided with one dose injection of "Methyl-prednisolon acetate" 40 milligrams plus 1 milliliter of "lidocaine"2 % (60 milligrams) in the maximal point tenderness. After injection, all involved wrists will be immobilized using fiberglass thumb spica casts.

Category

Treatment - Other

2

Description

Control group: All patients in this group will be provided with one dose injection of "Methyl-prednisolon acetate" 40 milligrams plus 1 milliliter of "lidocaine"2% (60 milligrams) in the maximal point tenderness.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam-Reza Clinic of Poursina Hospital

Full name of responsible person

Dr Mohsen Mardani Kivi

Street address

Imam-Reza Clinic, Poursina Hospital, Parastar Avenue

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Guilan University of Medical Sciences

Full name of responsible person

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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, Guilan 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**

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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