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 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
Country
Iran (Islamic Republic of)
Phone
+98 13 1321 1470
Email address
mardani@gums.ac.ir

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
City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Guilan University of Medical Sciences
Full name of responsible person
Dr. Abdolrasoul Sobhani, Research Chancellor of Guilan University of Medical Science
Street address
Vice Chancellor for Research, Guilan University of Medical Sciences, Namjou Avenue
City
Rasht
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
Guilan University of Medical Science
Full name of responsible person
Dr. Mohsen Mardani Kivi
Position
Assistant Professor
Other areas of specialty/work
Street address
Orthopedic Department, Poursina Hospital, Parastar Avenue.
City
Rasht
Postal code
Phone
+98 13 1321 1470
Fax
Email
dr_mohsen_mardani@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Guilan University of Medical Science
Full name of responsible person
Dr. Mohsen Mardani Kivi
Position
Assistant Professor
Other areas of specialty/work
Street address
Orthopedic Department, Poursina Hospital, Parastar avenue.
City
Rasht
Postal code
Phone
+98 13 1321 1470
Fax
Email
dr_mohsen_mardani@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Dr. Mohsen Mardani Kivi
Position
Orthopedic Surgeon, Assistant Professor
Other areas of specialty/work
Street address
Orthopedic Department, Poursina Hospital, Parastar Avenue
City
Rasht
Postal code
Phone
Fax
Email
dr_mohsen_mardani@yahoo.com
Web page address

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