

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Efficacy of corticosteroids injection in prevention of reflex sympathetic dystrophy and ulnar sided wrist pain in patients with acute extra articular distal radius fractures

Protocol summary

Summary

The aim of the present study is to determine the efficacy of corticosteroids to decrease or prevent the occurrence of ulnar sided wrist pain and/or complex regional pain syndrome in patients with distal radius fractures. The inclusion criteria will be as follows: 1. informed consent for entrance 2. adult (>18 y/o) with distal 1 inch radius fracture 3. intact or non displaced fractured ulnar styloid and 4. at least 6 months of follow up. The exclusion criteria will be as follows: 1. Pathological fractures 2. Severe osteoporosis 3. Any open surgical intervention. Patients referred to Dr Bamonar Hospital, meeting the entrance criteria will be divided into 4 random groups: 1. intact ulnar styloid, corticosteroid, 2. intact ulnar styloid, placebo, 3. fractured ulnar styloid, corticosteroid, and 4. fractured ulnar styloid, placebo. In the corticosteroid group, after anesthesia the patient will receive a corticosteroid injection (2 ampules of betamethazone L.A.) in the area of ulnar styloid and another one (2 ampules of dexamethazone) in the flexor tendons of the fingers proximal to wrist flexion crease, while in the placebo group only distilled water and lidocaine will be injected. Finger motion will be encouraged in all of the patients. The cast will be shortened 2 weeks later and removed after 6 weeks. Patients will be followed at 3 months intervals after the fracture for one year. All of the range of motions of the wrist and fingers will be recorded in every follow up and the patient will be asked about pain in the ulnar side of the wrist and will be observed for any signs and symptoms of reflex sympathetic dystrophy. In the 3 and 6 months and at the 1 year follow ups DASH score will be measured and recorded too. Finally the data will be analyzed by SPSS software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104062115N1**

Registration date: **2011-04-22, 1390/02/02**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-04-22, 1390/02/02

Registrant information

Name

Ali Reza Saied

Name of organization / entity

Kerman Neuroscience research center, Kerman
University of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Kerman University of
medical sciences, Kerman neuroscience center

Expected recruitment start date

2011-05-01, 1390/02/11

Expected recruitment end date

2012-05-01, 1391/02/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of corticosteroids injection in prevention of reflex sympathetic dystrophy and ulnar sided wrist pain in patients with acute extra articular distal radius fractures

Public title

Efficacy of corticosteroids injection in prevention of reflex sympathetic dystrophy and ulnar sided wrist pain in patients with acute extra articular distal radius fractures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: informed consent for entrance; adult (>18 y/o) with distal 1 inch radius fracture; intact or non displaced fractured ulnar styloid and at least 6 months of follow up. The exclusion criteria : pathological fractures; Severe osteoporosis; any open surgical intervention.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kerman University of Medical Sciences ethics committee

Street address

Thamasabad cross road, Vice chancellor for research, Kerman University of Medical Sciences, Kerman, Iran

City

Kerman

Postal code

Approval date

2011-03-16, 1389/12/25

Ethics committee reference number

EC/KNRC/89-93

Health conditions studied

1

Description of health condition studied

Distal radius fractures

ICD-10 code

S52.5

ICD-10 code description

Fracture of lower end of radius

Primary outcomes

1

Description

pain in the ulnar side of wrsit

Timepoint

3 months

Method of measurement

visual analogue score (the patient gives a number, 1 to 10, to the experienced pain)

Secondary outcomes

1

Description

Wrsit and forearm rotation compared to the opposite side

Timepoint

every 3 months

Method of measurement

observation and measurement

Intervention groups

1

Description

Injection of 2 vials of betamethasone LA in the triangular fibrocartilage complex and 16 mg of dexamethasone in the flexor digitorum sheet in intervention groups, regardless of ulnar styloid fracture

Category

Prevention

2

Description

Injection of lidoacaine and distilled water in the triangular fibrocartilage complex and flexor digitorum sheet in the control groups

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Kerman Dr Bahonar Hospital
Full name of responsible person
Dr Ali Reza Saied
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Person responsible for scientific inquiries

Contact

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Kerman University of Medical Sciences
Full name of responsible person
Dr Vahid Sheibani
Street address
Thamasbabad crossroad, Vice chancellor for research, Kerman University of Medical Sciences
City
Kerman
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, Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
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Associate professor of orthopedics
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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