

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effect of ulnar styloid fracture fixation in outcome of distal radius fractures

Protocol summary

Summary

The aim of this multi-center study is to compare some outcomes including pain, range of motion and grip strength of both fixation and non-fixation treatments of ulnar styloid in distal radius fractures. All adults with distal radius fractures and ulnar styloid fractures would meet the inclusion criteria. Sealed pockets will be used for randomization. Sample size has been estimated at least 78 cases. In intervention group, open pinning and long arm casting and in the control group long arm casting in supination position will be performed for six weeks. Physical therapy will be performed for 6 weeks after surgery. Patients will be followed up at 2, 4, 6, 8 weeks and 3, 6, 12 months after surgery. Ultimately pain, wrist's range of motion, ulnar styloid tenderness, Mayo score and Dash score will be assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061828510N1**
Registration date: **2016-07-13, 1395/04/23**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-13, 1395/04/23

Registrant information

Name

Ali Moradi

Name of organization / entity

Orthopedic Research Center of Ghaem Hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 3801 2638

Email address

moradial@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of ulnar styloid fracture fixation in outcome of distal radius fractures

Public title

The effect of ulnar styloid fracture fixation in treatment of radius fracture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Adults with ulnar styloid combined with distal radius fracture. Exclusion criteria: Age less than 18 years old; history of previous fracture or deformity; time between injury and admission more than two weeks; open fracture; fracture with nerve injury; patients with systemic disorders such as rheumatoid arthritis.

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: 78

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization will be done using sealed envelopes.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Ethics committee of Mashhad University of Medical Sciences, Daneshgah street, Mashhad, Iran

City

Mashhad

Postal code

Approval date

2016-06-22, 1395/04/02

Ethics committee reference number

IR.MUMS.SM.REC.1394.468

Health conditions studied

1

Description of health condition studied

distal radius fractures

ICD-10 code

S52.5, S52

ICD-10 code description

Fracture of lower end of radius, Fracture of lower end of both ulna and radius

Primary outcomes

1

Description

Grip strength

Timepoint

Physical examination before surgery

Method of measurement

Dynamometer

2

Description

Pain

Timepoint

Physical examination before surgery

Method of measurement

Vas score with questionnaire

Secondary outcomes

1

Description

Range of motion

Timepoint

2 weeks, 4 weeks, 6 weeks, 8 weeks , 3 months, 6 months and 12 months after surgery

Method of measurement

Physical examination

2

Description

DASH score

Timepoint

2 weeks, 4 weeks, 6 weeks, 8 weeks , 3 months, 6 months and 12 months after surgery

Method of measurement

questionnaire

3

Description

MAYO score

Timepoint

2 weeks, 4 weeks, 6 weeks, 8 weeks , 3 months, 6 months and 12 months after surgery

Method of measurement

Check list

4

Description

Pain

Timepoint

2 weeks, 4 weeks, 6 weeks, 8 weeks , 3 months, 6 months and 12 months after surgery

Method of measurement

Vas score with questionnaire

Intervention groups

1

Description

Fixation of ulnar styloid in distal radius fracture will use in intervention group

Category

Treatment - Surgery

2

Description

for control group we will not fix ulnar styloid in distal radius fracture

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Kamyab Hospital

Full name of responsible person

Ali Moradi

Street address

Shahid Kamyab Hospital, Nakhrisi Street, Mashhad, Iran

City

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2

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Ali Moradi

Street address

Emam Reza Hospital, Ebne Sina Street, Mashhad, Iran

City

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3

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

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Ghaem Hospital, Ahmad Abad Street, Mashhad, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Vice Chancellor for research of Mashhad University of

Medical Sciences, Daneshgah street, Mashhad, Iran

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Mashhad

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 of Mashhad 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

Orthopedic Research Center

Full name of responsible person

Ali Moradi

Position

Assistant Professor of Orthopedic Surgery

Other areas of specialty/work

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Full name of responsible person

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Other areas of specialty/work**Street address**

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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