

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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**

Mashhad

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**

Mashhad

3

**Recruitment center**

**Name of recruitment center**

Ghaem Hospital

**Full name of responsible person**

Ali Moradi

**Street address**

Ghaem Hospital, Ahmad Abad Street, Mashhad, Iran

**City**

Mashhad

**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

**City**

Mashhad

**Grant name**

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**Grant code / Reference number**

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**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**

**Street address**

Orthopedic Research Center, Ghaem Hospital, Ahmad Abad Street, Mashhad, Iran

**City**

Mashhad

**Postal code**

91766\_99199

**Phone**

+98 51 3841 7453

**Fax**

+98 51 3841 7453

**Email**

Moradial@mums.ac.ir

**Web page address**

<http://abjs.mums.ac.ir/>

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Orthopedic Research Center

**Full name of responsible person**

Ali Moradi

**Position**

Assistant Professor of Orthopedic Surgery

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**Web page address****Person responsible for updating data****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****Street address**

Orthopedic Research Center, Ghaem Hospital, Ahmad  
Abad Street, Mashhad, Iran

**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*