Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 met 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

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Orthopedic Research Center of Ghaem Hospital
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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
Dynomometer

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
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Shahid Kamyab Hospital, Nakhrisi Street, Mashhad, Iran
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2

Recruitment center
Name of recruitment center
Emam Reza Hospital
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3

Recruitment center
Name of recruitment center
Ghaem Hospital
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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
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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
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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