

Clinical outcomes investigation in ulna coronoid fractures with elbow instability

Submission date 01/03/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 05/04/2018	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/04/2018	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The coronoid process is a projection from the front of one of the bones in the arm that forms part of the elbow. Fracturing this can lead to instability of the elbow, which was traditionally thought to be classified by the size of the fracture. However recent studies have shown that the location of the fracture is also needed to help analyse the injury. The anteromedial facet is a central part of the coronoid process and fractures here typically vary, so the surgical approach to treat them is critical.

This study aims to report the surgical outcomes of participants with this type of fracture, by analysing their previous hospital records and results to suggest the best surgical approach.

Who can participate?

Adults with a fractured ulnar coronoid

What does the study involve?

All participants undergo surgery to fix their broken bone. The broken bone is reduced or put back in place, then an internal device is placed on the bone to hold it together. This may be screws, plates or pins depending on the injury. Participants attend follow up appointments 2 weeks, 3 months, 6 months, 1 year and 2 years after the operation where they undergo disability evaluation and X-ray imaging.

What are the possible benefits and risks of participating?

There are not any direct benefits or risks for those taking part in the study.

Where is the study run from?

Chang Gung Memorial Hospital-Linkou (Taiwan)

When is the study starting and how long is it expected to run for?

January 2007 – December 2017

Who is funding the study?

Chang Gung Memorial Hospital – Linkou (Taiwan)

Who is the main contact?
Dr Alvin Chao-Yu Chen (Scientific)
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
none

Study information

Scientific Title
Anteromedial fractures of the ulnar coronoid process: correlation between surgical outcomes and radiographic findings

Study objectives
This study aims to report the surgical outcomes of a consecutive case series and suggest an optimal surgical approach through a retrospective analysis of the surgical and radiographic findings of AMF fracture dislocation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Chang Gung Institutional Review Board, 11/09/2017, ref: IRB 201701326B0

Study design
Restrospective reviews on surgical outcomes of ulnar anteromedial facet fractures

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Fracture of forearm

Interventions

Open reduction and internal fixation of ulnar coronoid fractures is performed for all patients by the same surgeon. Fixation methods and implants are dependent on the fracture patterns including plate, screw, pin and wire and suture anchors. All participants attend regular outpatient clinic follow up appointments at 2 weeks, 3 months, 6 months, 1 year and 2 years.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Clinical functional outcomes are measured using the Mayo Elbow Performance Score (MEPs) and Shortened Disability of the Arm and Shoulder and Hand (quickDASH) scores two years after the operation.

Key secondary outcome(s)

Radiographic correlation with surgical approach and clinical results are assessed by an orthopaedic trauma surgeon and an elbow surgeon using retrospective review of elbow radiographs two years after the operation.

Completion date

31/12/2017

Eligibility**Key inclusion criteria**

1. Displaced anteromedial facet fracture of ulnar coronoid with instability

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Prior injury or surgery of the ipsilateral arm

Date of first enrolment

01/02/2007

Date of final enrolment

28/02/2014

Locations

Countries of recruitment

Taiwan

Study participating centre

Chang Gung Memorial Hospital-Linkou

5th, Fu-Shin St.

Kweishan District

Taiwan

333

Sponsor information

Organisation

Chang Gung Memorial Hospital-Linkou

ROR

<https://ror.org/02dnn6q67>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Chang Gung Memorial Hospital-Linkou

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study can be provided upon request from Alvin CY Chen (alvinchen@cgmh.org.tw) in Microsoft Word text files. It is available for 10 years after surgery for each participant. Consents from participants was obtained.

IPD sharing plan summary

Available on request