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Clinical outcomes investigation in ulna coronoid fractures with elbow instability

Submission date
01/03/2018

Recruitment status
No longer recruiting

Registration date
05/04/2018

Overall study status
Completed

Last Edited
04/04/2018

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/01/2007

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Displaced anteromedial facet fracture of ulnar coronoid with instability

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

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
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Sponsor information

Organisation
Chang Gung Memorial Hospital-Linkou

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02dnn6q67

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Chang Gung Memorial Hospital-Linkou

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/08/2018

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 for10 years after surgery for each participant. Consents from participants was obtained.

IPD sharing plan summary
Available on request