

# Long-term results of fixated olecranon fractures; evaluation of 235 patients with a minimum 1 year follow-up

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Fractures
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON43886

### Source

ToetsingOnline

### Brief title

LOFFT-study

### Condition

- Fractures
- Bone and joint therapeutic procedures

### Synonym

elbow fracture, proximal ulna fracture

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Noordwest Ziekenhuisgroep

**Source(s) of monetary or material Support:** Geld aanwezig in de maatschap

## Intervention

**Keyword:** Fixation, Fracture, Olecranon

## Outcome measures

### Primary outcome

To investigate the subjective functional outcome of the operated elbow measured with the DASH, after an olecranon fracture treated with TBW or PF with a minimum follow-up of one year.

### Secondary outcome

- To identify predictive factors of decreased functionality and range of motion of the operated elbow after fixation of an olecranon fracture.

## Study description

### Background summary

Olecranon fractures are a common type of fracture, with tension band wiring (TBW) as one of the oldest and most commonly used technique of internal fixation of olecranon fractures. Currently there is a shift detectable from the commonly used TBW to newer fixation techniques such as plate fixation (PF) and screws. However, only small studies are available on the functional outcomes of TBW and plate fixation. The best evidence currently available on this subject is a Cochrane review, which concluded that there is insufficient evidence to draw robust conclusions on the relative effects of the different surgical interventions such as TBW and PF. They stated that further evidence, including patient-reported data, is needed.

### Study objective

Aim of this study is to determine the functional outcome after a minimum of 1 year follow-up after fixation of the fractured olecranon with TBW or PF. Subgroup analyses will be done to investigate the assumed advantage of PF compared to TBW in comminuted fractures.

### Study design

The study will be a retrospective cohort study for all types of olecranon fractures (according to the Mayo-classification), treated with TBW or PF. Data will be collected from patient\*s medical records including clinical charts and radiology reports. A one-time consult will be held at our outpatient clinic for answering questionnaires and physical examination. This visit will take approximately one hour in total. The study will be done at the department of surgery at the Noordwest Ziekenhuisgroep.

### **Study burden and risks**

A one-time consult at the outpatient clinic will be scheduled for answering non-burdensome questionnaires and an easy, non-invasive examination of the elbow function of both elbows. The whole visit will take up to one hour maximum.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

- Having a history of an olecranon fracture which was treated with tension band wiring or plate fixation.
- Age: \*16 years at the moment of fracturing and \*18 years at the start of this study
- understanding Dutch

## Exclusion criteria

- Bilateral olecranon fracture
- Former surgery at one of the olecranons
- Diseases that can affect the elbow function (e.g. osteogenesis imperfecta, muscle disease, rheumatoid arthritis), except for osteoporosis.
- Mental disability that compromises postoperative treatment

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 17-10-2016

Enrollment: 235

Type: Actual

## Ethics review

Approved WMO

Date:	09-02-2016
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO	
Date:	16-12-2016
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

ID: 21638

Source: Nationaal Trial Register

Title:

### In other registers

Register	ID
CCMO	NL51401.094.15
Other	volgt nog
OMON	NL-OMON21638