

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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	-

Summary

ID

NL-OMON21638

Source

NTR

Brief title

LOFFT-study

Health condition

olecranon fractures, tension band wiring, plate fixation

Sponsors and support

Primary sponsor: none

Source(s) of monetary or material Support: Fund: Foreest Medical School, Alkmaar, the Netherlands

Intervention

Outcome measures

Primary outcome

Subjective functionality of the operated elbow measured by the DASH

Secondary outcome

The objective functionality of the elbow measured by the MEPI and range of motion of the operated elbow and compared to the non-operated elbow

Study description

Background summary

SUMMARY

Rationale:

Olecranon fractures are a common type of fracture with an annual incidence of approximately 1.15 to 1.2 per 10.000 population (age > 16 year) which constitutes of 18% of all proximal forearm fractures and occurs in all age groups, but with a predominance in the older age group. Tension band wiring (TBW) is the oldest and most commonly used technique of internal fixation for non-comminuted olecranon fractures. Currently, there is a shift detectable from this commonly used TBW to newer fixation techniques such as plate fixation (PF). However, there is insufficient evidence to draw robust conclusions on the subjective and objective effects of both TBW and PF, and therefore it is unknown if this shift is desirable and justified.

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), fixated 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 Medisch Centrum Alkmaar.

Study population:

All patients (≥16 year at the moment of fracturing and ≥18 years at the start of this study) who received TBW or PF for an olecranon fracture between 2004-2013 at the surgery department of a level one trauma centre (Medisch Centrum Alkmaar). We expect to included approximately 210 patients in the TBW-group and 25 patients in the PF-group, based on a

preliminary count.

Main study parameters/endpoints

The primary endpoint of this study is the subjective functionality of the operated elbow measured by the DASH score. The secondary endpoint will be the range of motion measured in degrees.

Study objective

There is no difference in terms of function between patients who had an olecranon fracture which has been operated with tension band wiring or with plate fixation

Study design

One

Intervention

- Mayo Elbow Performance Index (questionnaire)
- testing of range of motion
- Disabilities of the Arm, Shoulder and Hand (questionnaire)

Contacts

Public

Noordwest Ziekenhuisgroep

ALE Terstappen
Alkmaar Alkmaar
The Netherlands

Scientific

Noordwest Ziekenhuisgroep

ALE Terstappen
Alkmaar Alkmaar
The Netherlands

Eligibility criteria

Inclusion criteria

Patients (≥ 16 years) with an olecranon fracture which has been treated with TBW

or PF

- All patients should understand Dutch

Exclusion criteria

Bilateral olecranon fracture

- Former surgery of the affected olecranon

- Diseases that can affect the elbow function (osteogenesis imperfecta, muscle disease, rheumatoid arthritis), except for osteoporosis.

- Mental disability that compromises postoperative treatment

Study design

Design

Intervention model: Other

Masking: Open (masking not used)

Control: N/A , unknown

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-09-2016

Enrollment: 235

Type: Anticipated

Ethics review

Positive opinion

Date: 09-09-2016
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43886
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5756
NTR-old	NTR6022
CCMO	NL51401.094.15
OMON	NL-OMON43886

Study results