

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

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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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	-

Samenvatting

ID

NL-OMON21638

Bron

Nationaal Trial Register

Verkorte titel

LOFFT-study

Aandoening

olecranon fractures, tension band wiring, plate fixation

Ondersteuning

Primaire sponsor: none

Overige ondersteuning: Fund: Foreest Medical School, Alkmaar, the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Subjective functionality of the operated elbow measured by the DASH

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

One

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Noordwest Ziekenhuisgroep

ALE Terstappen
Alkmaar Alkmaar
The Netherlands

Wetenschappelijk

Noordwest Ziekenhuisgroep

ALE Terstappen
Alkmaar Alkmaar
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

or PF

- All patients should understand Dutch

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Onderzoeksmodel: Anders

Blinding: Open / niet geblindeerd

Controle: N.v.t. / onbekend

Deelname

Nederland

Status: Werving nog niet gestart

(Verwachte) startdatum: 01-09-2016

Aantal proefpersonen: 235

Type: Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 09-09-2016

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43886

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten