Arthroplasty in three- or four-part proximal humerus fracture: hemi or reverse?

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Our hypothesis is that reverse arthroplasty has a better functional outcome and patient satisfaction than hemi-arthoplasty in patients with a three or four part proximal humerus fracture.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21570

Bron
NTR

Verkorte titel
Proshere

Aandoening

proximal humerus fracture
arthroplasty

Ondersteuning

Primaire sponsor: Medisch Centrum Alkmaar
Onze Lieve Vrouwe Gasthuis, Amsterdam
Reinier de Graaf Ziekenhuis, Delft
Atrium Medisch Centrum, Heerlen
Overige ondersteuning: Medisch Centrum Alkmaar
Onze Lieve Vrouwe Gasthuis, Amsterdam
Reinier de Graaf Ziekenhuis, Delft
Atrium Medisch Centrum, Heerlen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Constant shoulder score.

Toelichting onderzoek

Achtergrond van het onderzoek

Proximal humerus fractures account for 10% of all fractures and in the elderly population it is the 3rd most common fracture. The treatment of 3- or 4-part fractures, as described by Neer, consists of conservative treatment, plate fixation, percutaneus fixation or arthroplasty. However, the literature does not support valid decision making among surgical procedures, or even between operative and non-operative treatment. Especially in displaced three and four part proximal humerus fractures the ideal treatment sequel is still undefined. Regardless of the primary treatment, operative or non-operative, the complex proximal humerus fractures result in a functional impairment of the shoulder and arm resulting in a substantial negative effect upon the patients' quality of life.

Operative management of these fractures with osteosynthesis often provides good initial fracture reduction, but with a risk of secondary loosening in osteoporotic bone or humeral head osteonecrosis, leading to high complication and re-intervention rates. A reliable alternative is shoulder arthroplasty, with hemi-arthroplasty as the reference treatment, which is a safe surgical procedure with relatively low complication rates. An advantage in quality of life in favor of hemiarthroplasty compared to non-operative treatment in elderly patients with a displaced 4-part fracture of the proximal humerus has been demonstrated. Although good outcomes regarding pain are described, the outcomes regarding restoration of function are still poorly predictable. The main factor leading to a poor functional outcome is the lack of healing of the tubercles after shoulder arthroplasty in fracture patients.

Reversed shoulder arthroplasty, which is less dependent on the function of the rotator cuff, is a new alternative for hemi-arthroplasty in fracture patients. It is a common procedure in other shoulder disorders as, osteoarthritis and cuff tear arthropathy, with good functional results. Without the necessity of an adequate cuff and vascularised tubercula reversed shoulder arthroplasty can possibly provide a better functional and a better predictable outcome with the same pain reduction. Up until now the reported outcomes of reversed

shoulder prosthesis in fracture patients seems promising in single series. However the overall are not generally better than those reported for a primary hemi arthroplasty and randomized trials are lacking.

Therefore, we designed a randomized controlled trial to determine whether reversed shoulder arthroplasty may lead to a better functional outcome than hemi-arthoplasty among patients with a three or four part proximal humeral fracture. This paper reports the study design of the Proshere-trial (arhtoplasty in PROximal humerus fractureS; HEmi or REverse?)

Doel van het onderzoek

Our hypothesis is that reverse arthroplasty has a better functional outcome and patient satisfaction than hemi-arthoplasty in patients with a three or four part proximal humerus fracture.

Onderzoeksopzet

Follow-up on both groups will take place at 6 weeks, 3, 6 and 12 months after commencement of treatment.

Onderzoeksproduct en/of interventie

1. Aequalis fracture prosthesis;

2. Aequalis reverse fracture prosthesis.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients of 65 years and above with an isolated 3- or 4-part (displaced) proximal humerus fracture who are candidates for primary shoulder arthroplasty. Included patients must have complete understanding of the Dutch language.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Primary exclusion criteria are age less than 65 and an ASA-score 4 or higher. Patients with a previous osteosynthesis of the shoulder, as well as a delay of more than 1 month will also be excluded. Patients who lack understanding of the Dutch language are excluded. Secondary exclusion criteria is a glenoid bone defect greater than 30% or more than 15 degrees of retroversion of the glenoid.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2010

Aantal proefpersonen:	52
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-12-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3060
NTR-old	NTR3208
Ander register	METC-NH / CCMO : M09-040 / NL 26142.094.09;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A