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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21570

Source
NTR

Brief title
Proshere

Health condition

proximal humerus fracture
arthroplasty

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Onze Lieve Vrouwe Gasthuis, Amsterdam
Reinier de Graaf Ziekenhuis, Delft
Atrium Medisch Centrum, Heerlen
Source(s) of monetary or material Support: Medisch Centrum Alkmaar
Onze Lieve Vrouwe Gasthuis, Amsterdam
Reinier de Graaf Ziekenhuis, Delft
Atrium Medisch Centrum, Heerlen

Intervention

Outcome measures

Primary outcome

Constant shoulder score.

Secondary outcome

1. DASH score;

2. SF12;

3. VAS pain.

Study description

Background summary

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?)

Study objective

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.

Study design

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

Intervention

1. Aequalis fracture prosthesis;

2. Aequalis reverse fracture prosthesis.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2010
Enrollment:	52

Type:	Anticipated

Ethics review

Positive opinion

Date:	18-12-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results

Summary results

N/A