Hemiarthroplasty versus Osteosynthesis in humeral fractures (HOMERUS): A Multicenter Randomized trial.

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Hemiarthroplasty will show quicker recovery of functional capacity of the affected upper limb in 2 years compared with open reduction and internal fixation with an angle stable locking compression plate in the treatment of dislocated three and four...

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

Samenvatting

ID

NL-OMON23688

Bron
NTR

Verkorte titel
HOMERUS

Aandoening

proximal humeral fracture, shoulder fracture, hemiarthroplasty, angle stable locking compression plate osteosynthesis
proximale humerusfractuur, schouderprothese

Ondersteuning

Primaire sponsor: University Medical Center Groningen, Department of Orthopaedic Surgery-Traumatology
Overige ondersteuning: University Medical Center Groningen, Department of Orthopaedic Surgery-Traumatology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Speed of recovery of functional capacity of the affected upper limb measured with the DASH.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

The optimal surgical management of three- and four-part proximal humeral fractures in elderly osteoporotic patients remains controversial. Mostly used techniques are hemiarthroplasty and angle stable locking compression osteosynthesis. In literature there is no evidence available showing advantage of angle stable locking compression plate osteosynthesis compared to hemiarthroplasty regarding speed of recovery of functional capacity, pain, patient satisfaction,functional outcome, quality of life, and complications.

Objective:

The objective of this study is to conduct a randomized controlled trial to compare hemiarthroplasty with open reduction and internal fixation with an angle stable locking compression plate in the treatment of dislocated three- and four-part fractures of the proximal humerus in the elder population. Primary outcome parameter is speed of recovery of functional capacity of the effected upper limb. We hypothesize that hemiarthroplasty shows quicker recovery of functional capacity. Secondary outcome parameters are pain,patient satisfaction, functional outcome, quality of life, radiographic evaluation and complications.

Study design:

A prospective, non-blinded, multicentric randomized controlled trial will be conducted to allocate patients to either hemiarthroplasty or open reduction and internal fixation with angle stable locking compression plate osteosynthesis to study speed of recovery of functional capacity and other secondary outcomes.

Study population:

Patients to be included suffer from three- or four- part fracture of the proximal humerus according to the Neer classification with more than 5 mm dislocation in one of the fracture-planes and are aged above 60 years. Patients with a fracture existing more than 14 days, ASA IV-V, multitrauma (ISS>16), pathological fracture, previous surgery on the injured shoulder, severely deranged function caused by a previous disease, head-split proximal humerus fracture and unwillingness or inability to follow instruction are excluded.

Intervention:

One group will be treated by hemiarthroplasty and the other group will be treated by open reposition and internal fixation with a angle stable locking compression plate.

Measurements:

In this study the following outcome parameters will be assessed: speed of recovery of functional capacity of the effected upper limb (primary outcome), pain, patient satisfaction, functional outcome, quality of life, radiographic evaluation and complications (secondary outcomes).

Doel van het onderzoek

Hemiarthroplasty will show quicker recovery of functional capacity of the affected upper limb in 2 years compared with open reduction and internal fixation with an angle stable locking compression plate in the treatment of dislocated three and four part fractures of the proximal humerus.

Onderzoeksopzet

Baseline, 3 months, 6 months, 9 months, 12 months, 24 months.

Onderzoeksproduct en/of interventie

1. Hemiarthroplasty;

2. Angle stable locking compression plate osteosynthesis.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. 3- and 4- fragment fracture proximal humerus according to the Neer classification;

2. >5 mm dislocation in one of the fracture planes;

3. >60 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Fracture existing more than 14 days;

2. ASA IV-V;

3. Multitrauma , ISS > 16;

4. Pathological fracture;

5. Previous surgery on injured shoulder;

6. Severely deranged function caused by a previous disease;

7. “Head Split”fracture proximal humerus;

8. Unwillingness or inability to follow instructions.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2010
Aantal proefpersonen:	134
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-08-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 35023
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2354
NTR-old	NTR2461
CCMO	NL29934.042.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35023

Resultaten

Samenvatting resultaten
N/A