Three- and four-part fracture of the proximal humerus in the elderly. Angle stable locking compression plate osteosynthesis versus hemiarthroplasty.

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON35023

Source
ToetsingOnline

Brief title
Hemiarthroplasty vs Osteosynthesis in huMEral fRactUreS;HOMERUS-study

Condition

- Bone and joint therapeutic procedures

Synonym
3- and 4 part fracture of the proximal humerus/ shoulderfracture

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: -angle stable locking compression plate osteosynthesis, -hemiarthroplasty, -proximal humeral fractures

Outcome measures

Primary outcome

Primary outcome parameter is speed of recovery of functional capacity of the

affected upper limb.

Secondary outcome

Secondary outcomes are: pain, patient satisfaction, functional outcome, quality

of life, radiographic evaluation and complications

Study description

Background summary

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.

Study 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.

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.

Study burden and risks

The methods of treatment in this study are contemporary *common current treatment* methods. There can be found two main risk factors. The first is the possible negative effects of exposure to radiation when making a CT-scan. Nevertheless, this is a common used and necessary investigation in characterizing the fracture type and in choosing the forthcoming treatment method. The second is the possibility of appearence complications after operative treatment of three- and four- part fractures of the proximal humerus. In literature, operative treatment is recommended and no significant difference in number or gravity in the appearance of complications between treatment with hemiarthroplasty or treatment with angle stable locking compression plate osteosynthesis can be found. Furthermore, patients will be seen three times during an outpatient clinic visit and will be asked twice to fill in a questionnaire that will be send to their home address.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	134
Type:	Anticipated

Ethics review

Approved WMO

Date:	28-04-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23688
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL29934.042.09
OMON	NL-OMON23688