Arthroplasty in three and four part proximal humeral fracture: hemi or reverse?
Prospective randomised clinical trial

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Compare hemi-arthroplasty with reverse arthroplasty in the treatment for displaced three- or four-part proximal humerus fractures

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON39124

Source
ToetsingOnline

Brief title
Arthroplasty in proximal humeral fracture: hemi or reverse?

Condition

- Fractures

Synonym
proximal humerus fracture, shoulder fracture

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: fracture, hemi-arthroplasty, humeral, reverse

Outcome measures

Primary outcome

Constant and DASH shoulder scores, ROM and VAS-pain.

Secondary outcome

Secondary parameters are complications and revision rate

Study description

Background summary

The ideal sequel in the treatment of displaced three and four part proximal humerus fractures is still undefined. Hemi-arthroplasty is a reliable treatment for pain reduction, however generally with a poor range of motion. Without the necessity of an adequate cuff and vascularised tubercula reverse shoulder arthroplasty can possibly provide a better functional outcome with the same pain reduction.

Study objective

Compare hemi-arthroplasty with reverse arthroplasty in the treatment for displaced three- or four-part proximal humerus fractures

Study design

Prospective randomized clinical trial

Intervention

Operative treatment by either Aequalis fracture prosthesis or Aequalis reverse fracture prosthesis.

Study burden and risks

The general operative risks are equal in both groups. The complication risk, as infection, instability en neuralpraxia, is comparable. Potential benefits in

the reverse group is a greater range of motion with equal pain reduction.
The number of visits is equal compared with standard procedure, however X-rays and questionnaires will be taken more regularly.

Contacts

Public
Medisch Centrum Alkmaar

Wilhelminalaan 12
Alkmaar 1815 JD
NL
Scientific
Medisch Centrum Alkmaar

Wilhelminalaan 12
Alkmaar 1815 JD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients of 65 years and above with a three or four part proximal humerus fracture, ASA 1-3 and within one month after the trauma.

Exclusion criteria

patients younger than 65 years, ASA-4 and a delay of moren than one month

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:	Recruitment stopped
Start date (anticipated):	01-06-2010
Enrollment:	68
Type:	Actual

Ethics review

Approved WMO Date:	22-12-2009
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	20-08-2010
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	15-07-2011
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

Approved WMO Date:	24-03-2014
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

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
CCMO	NL26142.094.09