Primary hemiarthroplasty versus conservative treatment for comminuted fractures of the proximal humerus in the elderly - A Multicenter Randomized trial

Published: 11-06-2009
Last updated: 15-05-2024

Primary objectiveTo compare the Constant scores (reflecting functional outcome and pain) at one year after primary hemiarthroplasty versus non-operative treatment in patients over 65 years of age who sustained a complex humeral fracture.Secondary…

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

Summary

ID

NL-OMON41420

Source
ToetsingOnline

Brief title
ProCon trial

Condition

- Fractures

Synonym
Comminutive proximal humeral fractures; Shoulder fracture

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

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

Intervention

Keyword: Hemiarthroplasty, Multicenter study, Proximal humeral fracture

Outcome measures

Primary outcome

Constant score

Secondary outcome

DASH score, including optional module for sports/music performance

Pain level at both sides (VAS)

Secondary intervention

Radiographic healing

Mortality

Complication rates in HA group: infection, neurovascular injury, malpositioning of the prosthesis, asceptic loosening of the prosthesis, dislocation of the tuberculi

Complication rates in control group: malunion, nonunion, secondary dislocation, symptomatic avascular necrosis (AVN) of the humeral head

SF-36

EQ-5D

Costs and cost-effectiveness

Study description

Background summary

Fractures of the proximal humerus are common injuries in the elderly. The incidence is approximately 6.6 per 1000 person years. Most of these fractures can be treated with non-operative means and careful early motion. However, the treatment of complex fractures like selected three-or four-part fractures and split fractures of the humeral head is a demanding and unresolved problem. Locking plates have recently been introduced and they appear to offer improved fixation. However, especially in elderly patients the prevalence of screw cut-out ranges from 11 to 43% due to fracture collapse. This may ultimately lead to higher rates of revision surgery. Therefore, it seems reasonable to treat these complex fractures primarily with a prosthesis or non-operatively in a population of elderly patients.
Primary hemiarthroplasty and non-operative treatment of complex proximal humeral fractures have been described in a number of studies with varying functional results. Stableforth et al. performed a randomized study comparing hemiarthroplasty with conservative management in a total of 32 patients. The results revealed less pain and better overall function in the hemiarthroplasty group. However, this study had methodological limitations because of indistinct inclusion criteria and a difference in age between the two intervenion arms at baseline, and may therefore not be generalizable. To our notice no other randomized controlled trial has been performed to compare hemiarthroplasty and non*operative treatment of complex fractures of the proximal humerus.

Study objective

Primary objective
To compare the Constant scores (reflecting functional outcome and pain) at one year after primary hemiarthroplasty versus non-operative treatment in patients over 65 years of age who sustained a complex humeral fracture.

Secondary objectives
1. To compare the Constant scores (reflecting functional outcome and pain) at six months and two year after primary hemiarthroplasty versus non-operative treatment in patients over 65 years of age who sustained a complex humeral fracture
2. To examine the effect of primary hemiarthroplasty versus non-operative treatment on the degree of disabilities of the arm, shoulder and hand (DASH score) as well as on sports/music performance (DASH optional module)
3. To examine the effect of primary hemiarthroplasty versus non-operative treatment on the level of pain experienced by the patients (VAS)
4. To examine the effect of primary hemiarthroplasty versus non-operative treatment on the rate of secondary interventions, complications and mortality
5. To examine the effect of primary hemiarthroplasty versus non-operative treatment on health-related quality of life (SF-36, EQ-5D)
6. To assess the costs and cost-effectiveness ratio of primary hemiarthroplasty versus non-operative treatment
7. To identify the healing and position of the tuberculi based on CT and

radiographs

Study design

Multicenter randomized controlled trial

Intervention

One group will receive a hemiarthroplasty (Affinis® Fracture shoulder endoprosthesis (Mathys AG Bettlach)).
Critical aspects of the surgical procedure will be standardized. After surgery, patients are allowed to use a sling for 2 days to one week. Patients will receive after-treatment following a standardized approach. Anteflexion and elevation exercises may be started immediately if tolerated. Rotation exercises against resistance are not allowed during the first six weeks after surgery.

The other group will be treated non-operatively.
The affected arm will be put in a collar and cuff for three weeks. At one week after fracture circumduction exercises will start. At three weeks after fracture mobilization will be initiated by practicing under supervision of a physical therapist. Physical therapy sessions will be held at regular intervals, preferably 2 times a week during 12 weeks. The exact frequency and duration of physical therapy will largely depend upon the extent of functional recovery. This will be left at the discretion of the therapist.

Study burden and risks

Both interventions are standard of care treatment modalities.

The clinic follow-up visits at t=1, 3 and 6 weeks, and 3, 6, 12 and 24 months are part of Standard of Care. The same holds true for the X-rays at t=1,3 and 6 weeks, and 3 and 12 months and the pre-operative CT-scan (for fracture classification).

For research purposes, one single CT scan of the schoulder will be made at 12 monthts in order to assess the degree of radiographic healing. The effective radiation due to this CT scan is mild. An additional risk associated with participating in this trial is the completion of a set of questionnaires. There are no risks involved in that.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients meeting the following inclusion criteria are eligible for enrolment:
1. Adult men or women aged 65 years and older (with no upper age limit)
2. Fracture of the humeral head
3. Selected three-part (Hertel classification type 9, 10, 11), selected four-part (Hertel type 12), anatomical neck (Hertel type 2), or split-head fractures of the humeral head in the judgement of the attending surgeon. All fractures should be classified according to the binary description system, based on 3D CT reconstructions
4. Operative treatment within 21 days of presenting to the emergency department (if randomized for HA)
5. Provision of informed consent by patient
6. Assurance that the surgeon who will perform HA has attended the pre-trial HA course.

Exclusion criteria

If any of the following criteria applies, patients will be excluded:
1. Polytraumatized patients
2. Patients with an additional traumatic injury of the affected arm

3. Patients with pathological, recurrent or open fractures
4. Patients with an impaired shoulder function (i.e., stiff or painful shoulder, neurologic disorder of the upper limb, or diagnosed rotator cuff impairment) prior to the injury
5. Retained hardware around the affected humerus
6. Patients with a disorder of bone metabolism other than osteoporosis (i.e., Paget*s disease, renal osteodystrophy, osteomalacia)
7. Moderate or severe cognitively impaired patients (i.e., Mini-Mental Status Examination (MMSE) Six Item Screener with 3 or more errors)
8. Likely problems, in the judgment of the investigators, with maintaining follow-up (e.g., patients with no fixed address will be excluded)
9. Insufficient comprehension of the Dutch language to understand a rehabilitation program and other treatment information in the judgment of the attending physician.

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):	15-06-2009
Enrollment:	65
Type:	Actual

Ethics review

Approved WMO

Date:	11-06-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	21-04-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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: 24819
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL26320.078.09
OMON	NL-OMON24819