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

No registrations found.

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

Summary

ID

NL-OMON24819

Source
Nationaal Trial Register

Brief title
ProCon

Health condition

Nederlands:
proximale humerusfractuur
schouderfractuur
schouderprothese

Engels:
proximal humeral fracture
shoulder fracture
shoulder prosthesis

Sponsors and support

Primary sponsor: Erasmus MC, University Medical Center Rotterdam, Department of

Surgery-Traumatology
Erasmus MC, Medical Ethical Committee (METC)
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Constant Score.

Secondary outcome

1. Disabilities of the Arm, Shoulder and Hand (DASH) score, including optional module for sports/music performance;

2. Pain level (Visual Analog Scale, VAS);

3. Radiographic healing;

4. Rate of secondary interventions;

5. Complication rates;

6. Mortality rate;

7. Health-related quality of life (Short-Form 36 (SF-36) and EuroQol-5D (EQ-5D));

8. Costs;

9. Cost-effectiveness.

Study description

Background summary

BACKGROUND

Fractures of the proximal humerus are common injuries in the elderly. The incidence is approximately 6.6 per 1,000 person years. Most of these fractures can be treated with non-operative means and careful early motion. However, the treatment of comminuted 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 comminuted fractures primarily with a prosthesis or non-operatively in a population of elderly patients.

Primary hemiarthroplasty and non-operative treatment of comminuted 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 intervention 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 comminuted fractures of the proximal humerus.

AIM

The primary objective of this RCT is 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 comminuted humeral fracture.

Secondary aims are to assess effects on primary hemiarthroplasty versus conservative treatment on the degree of disabilities of the arm, shoulder and hand (DASH score), the level of pain (VAS), rate of secondary interventions, complications and mortality, health-related quality of life (SF-36, EQ-5D), and the time to radiographic healing and position of the tuberculi based on CT and radiographs. The costs and cost-effectiveness of both interventions will be determined.

STUDY DESIGN

Multi-center randomized clinical trial

POPULATION

Patients (65 years or older) with a comminuted proximal humeral fracture.

INTERVENTIONS

1) Hemiarthroplasty (Affinis® Fracture shoulder endoprosthesis). 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.

2) Conservative treatmentThe 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.

ENDPOINTS

Primary outcome (Constant Score) and secondary outcomes (DASH, pain, radiographic healing, secondary intervention rates, complication rates, mortality rates, SF-36, and EQ-5D) will be compared at baseline, at 1, 3 and 6 weeks, and at 3, 6, 12 and 24 months after start of treatment, using both univariate and multivariable analyses. Costs for (in)formal healthcare consumption will be determined for both interventions, Cost-effectiveness will be expressed as cost per quality of life year (QALY) gained.

Study objective

Hemiarthroplasty will result in higher Constant scores (reflecting better functional outcome with less pain) at 1 year compared with non-operative treatment of complex humeral fractures in the elderly.

Study design

Baseline, 1 week, 3 weeks, 6 weeks, 3 months, 6 months, 12 months, 24 months.

Intervention

1. Hemiarthroplasty (Affinis® Fracture shoulder endoprosthesis);

2. Conservative treatment.

Contacts

Public
Erasmus MC, dept. of Surgery-Traumatology

Mailbox H-822k
's-Gravendijkwal 230, 3015 CE Rotterdam
P.O. Box 2040
D. Hartog, den
Erasmus MC, dept. of Surgery-Traumatology
Mailbox H-822k
's-Gravendijkwal 230, 3015 CE Rotterdam
P.O. Box 2040
Rotterdam 3000 CA
The Netherlands
+31-10 7031050
Scientific
Erasmus MC, dept. of Surgery-Traumatology
Mailbox H-822k
's-Gravendijkwal 230, 3015 CE Rotterdam
P.O. Box 2040
D. Hartog, den
Erasmus MC, dept. of Surgery-Traumatology
Mailbox H-822k
's-Gravendijkwal 230, 3015 CE Rotterdam
P.O. Box 2040
Rotterdam 3000 CA
The Netherlands
+31-10 7031050

Eligibility criteria

Inclusion criteria

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 judgment 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 hemiarthroplasty);

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

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.
Exclusion of a patient because of enrolment in another ongoing drug or surgical intervention trial will be left to the discretion of the attending surgeon, on a case-by-case basis.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	15-06-2009
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-09-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41420
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1923
NTR-old	NTR2040
CCMO	NL26320.078.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON41420

Study results

Summary results

Den Hartog D, Van Lieshout EMM, Tuinebreijer WE, Polinder S, Van Beeck EF, Breederveld RS, Bronkhorst MWGA, Eerenberg JP, Rhemrev S, Roerdink WH, Schraa G, Van der Vis HM, Van Thiel TPH, Patka P, Nijs S, Schep NWL. Primary hemiarthroplasty versus conservative treatment for comminuted fractures of the proximal humerus in the elderly (ProCon): A Multicenter Randomized Controlled trial. BMC Musculoskelet Disord 2010;11(1):97.