Randomised Clinical Trial comparing cemented and hydroxy-apatite coated uncemented hemi-arthroplasty in the elderly patient with a proximal intracapsular femoral fracture.

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The objective of this prospective randomised multi-center study is to compare the clinical outcome of the cemented and hydroxy-apatite coated uncemented hemi-arthroplasty for patients with a proximal intracapsular femoral fracture and the indication...

Ethical review	Approved WMO
Status	Completed
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON33945

Source
ToetsingOnline

Brief title
cemented versus hydroxy-apatite coated uncemented hemi-arthroplasty

Condition

- Bone and joint therapeutic procedures

Synonym
broken hip, proximal intracapsular femoral fracture

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: geen sponsoring;ook niet door ter beschikking stellen van de protheses

Intervention

Keyword: cemented, fracture, hemi-arthroplasty, uncemented

Outcome measures

Primary outcome

The primary outcome is a composite endpoint of Serious Adverse Events:

mortality, cardiac arrest, clinically pulmonary embolism, myocard infarct and

CVA.

Secondary outcome

Secundary study parameters are post-surgery delirium, complications and

mobilisation. A cost-effectiveness analysis will be completed.

Study description

Background summary

Published studies comparing morbidity/mortality and post-operative functional outcome after cemented or uncemented hemi-arthroplasty are mostly retrospective. So far no study has been published comparing the newer, commonly used, hydroxy-apatite coated hemi-arthroplasty. The recent Cochrane Review on this subject concludes that no definitive conlusions can be made and further well-conducted randomised trials are required

Study objective

The objective of this prospective randomised multi-center study is to compare the clinical outcome of the cemented and hydroxy-apatite coated uncemented hemi-arthroplasty for patients with a proximal intracapsular femoral fracture and the indication of a hemi-arthroplasty.

Study design

Prospective, randomized, single-blinded study lasting 3 to 4 years (2-3 years accrual and one year of follow-up).
The indicated patientgroup is defined as patients of 65 years or older with a proximal intracapsular femoral fracture and the indication of a hemi-arthroplasty.
After inclusion a Barthel index, Parker and Palmer mobility score, MMSE and DOS questionnaire will be taken pre-operatively.
Blinded envelopes will be used to randomize between a cemented or hydroxy-apetite coated uncemented hemi-arthroplasty. The patient and paramedics will not be told which one of the two hemi-arthroplasty is placed.
During hospital stay the next variables will be recorded: mortality, complications (infection, thrombosis, pulmonary embolism, CVA, delirium, cardiac dysfunction/attack), mobilisation, pain (NRS), length of hospital stay (medical indicated), DOS- and DOM-score, Barthel index and Parker and Palmer mobility score at discharge.
Polyclinic controls will be after 6 weeks, 3 months and 1 year post-surgery. Mortality, complications (infection, thrombosis, pulmonary embolism), pain (NRS), Barthel index and Parker and Palmer mobility score will be recorded. An X-ray of the hip will be made after 1 day, 3 months and 1 year post-surgery.

Intervention

Cemented versus hydroxy-apetite coated uncemented hemi-arthroplasty by patients of 65 years or older with a proximal intracapsular femoral fracture and the indication of a hemi-arthroplasty.

Study burden and risks

Cemented or hydroxy-apatite coated uncemented hemi-arthroplasty are both commonly accepted treatments.
If the patient does not want to participate in the study, he or she still has to be treated with placement of (the same) hemi-arthroplasty.
Participation with this study does not imply extra burden or risks, except for some questionarries, for the patient.

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

All patients from 65 years and older, who have an indication for a hemi-arthroplasty

Exclusion criteria

Primary bone tumour or bone metastasis causing the proximal intracapsular femoral fracture
Multiple trauma patient
Patients suffering from coxarthrosis at the fractured side
Revision of osteosyntesis

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	17-09-2009
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO

Date:	21-04-2009
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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: 21470
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL23995.098.08

Study results

Date completed: 27-08-2012

Summary results
Trial ended prematurely