

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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In the elderly patient with a proximal intracapsular femoral fracture a hydroxy-apatite coated uncemented hemi-arthroplasty will lead to a lower mortality rate and less severe complications compared to a cemented hemi-arthroplasty.

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

Summary

ID

NL-OMON21470

Source

Nationaal Trial Register

Brief title

Cemented versus hydroxy-apatite coated uncemented hemi-arthroplasty.

Health condition

proximal intracapsular femoral fracture, mediale collum fractuur, cement, hydroxy-apatite coated uncemented, hemi-arthroplasty, kophals prothese

Sponsors and support

Primary sponsor: Haga Ziekenhuis
LUMC

Source(s) of monetary or material Support: Haga Ziekenhuis
LUMC

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Secondary study parameters are post-surgery delirium, surgical time, radiological evaluation, pain, complications and mobilisation.

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 conclusions can be made and further well-conducted randomised trials are required

Study objective

In the elderly patient with a proximal intracapsular femoral fracture a hydroxy-apatite coated uncemented hemi-arthroplasty will lead to a lower mortality rate and less severe complications compared to a cemented hemi-arthroplasty.

Study design

0-30 days (Serious Adverse Events), 6 weeks, 12 weeks and 1 year follow-up.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

The elderly patient with a proximal intracapsular femoral fracture who should be treated with a hemi-arthroplasty.

Exclusion criteria

Multiple trauma patient
Pathological fracture
Symptomatic coxarthrosis at the ipsilateral side
Osteosynthesis revision.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control: Active

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 01-07-2009
Enrollment: 400
Type: Anticipated

Ethics review

Positive opinion
Date: 28-04-2009
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 33945
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1681
NTR-old	NTR1782
CCMO	NL23995.098.08
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON33945

Study results

Summary results

N/A