Cemented versus non-cemented hemiarthroplasty of the hip as a treatment for a displaced femoral neck fracture; a multi center randomised trial.

No registrations found.

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

Summary

ID

NL-OMON22861

Source
NTR

Brief title
To Cement or Not?

Health condition

hemiarthroplasty
kophalsprothese
cement
cementless
ongecementeerd
femoral neck fracture
mediale collum fractuur

Sponsors and support

Primary sponsor: The study will be conducted at the Orthopaedic Departments of:
-Reinier de Graaf Gasthuis Delft
-Ziekenhuis Rijnstate Arnhem
-Canisius Wilhelmina Ziekenhuis Nijmegen
-Elisabeth Ziekenhuis Tilburg.

Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

1. Duration of surgery is defined as skin-to-skin surgical time, measured in minutes;

2. Functional outcome is measured by the Time-Up-and Go (TUG) score and the Groningen Activity Restriction Scale (GARS);

3. Postoperative mid thigh pain is measured by a 4 -point ordinal scale (non/mild/ moderate/ severe) score. Mid thigh pain is defined as pain explicit in the front and mid part of the femur.

Secondary outcome

1.Living situation at final follow up, measured in percentage of pre-fracture situation;

2. Self reported health-related quality of life, measured by the SF 12;

3. Standard radiological evaluation of hemiarthroplasty and cement positioning and adequate size of the hemiarthroplasty measured on plain AP and axial X-rays of the operated hip. Adequate AP positioning is defined as less than 10 degrees varus or valgus. Adequate axial positioning is defined as 0 to 15 degrees anteversion.

Study description

Background summary

Based on the recent Cochrane analysis no preference can be found for using a non cemented or a cemented hemiarthroplasty. This study has been designed to compare a cemented and a non cemented hemiarthroplasty as a treatment for a displaced femoral neck fracture. The results of this trial will be published as soon as they become available.

Study objective

We hypothesise that not using bone cement in hemiarthroplasty for proximal femoral fractures in elderly patients will at least have comparable functional outcomes and complications with a shorter operation time.

Study design

1. Follow up of 1 year;

2. Measurements at 0,6,12 and 52 weeks.

Intervention

Randomisation to either a cemented hemiarthroplasty Muller (Zimmer) or a non cemented hemiarthroplasty, DB 10 (Biomet).

Contacts

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Eligibility criteria

Inclusion criteria

1. Age > 70 years;

2. Displaced femoral neck fracture;

3. ASA I- IV patient.

Exclusion criteria

1. Pathological fracture;

2. Fracture > 7 days old;

3. ASA V patient.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2008
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-10-2008
Application type:	First submission

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
NTR-new	NL1447
NTR-old	NTR1508
Other	NL19200.098.07 : ABR number

Study results

Summary results
N/A