Vergelijkende studie naar slijtage van polyethyleen van heupprothesen bij jonge patiënten.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29039

Source
Nationaal Trial Register

Brief title
X3-trial

Health condition

Total hip arthroplasty; total hip prosthesis; acetabulum; cement; wear; revision.

Sponsors and support

Primary sponsor: Radboud University Nijmegen Medical Centre, department of Orthopaedics.
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Radiological measurements on wear patterns. It is not expected that any difference will be measurable within 5 years after surgery.

Secondary outcome

Revision for aseptic loosening, osteolysis on radiographs.

Study description

Background summary

Wear of the polyethyelene cup is a main reason for long-term failure of total hip arthroplasties. Especially in young patients, polyethylenes with high wear resistance are mandatory. In this study, we compare the wear of cups made of X3 crosslinked polyethylene versus traditional polyethyelene. At the surgical theatre, patients are randomized in two groups; traditional versus X3-cups. Except for the type of polyethyelene, all other parts of the surgery and rehabilitation are equal. Clinical and radiological follow-up will be used to determine aseptic loosening, osteolysis and wear patterns.

Study objective

Wear of the polyethyelene cup is a main reason for long-term failure of total hip arthroplasties. Especially in young patients, polyethylenes with high wear resistance are mandatory. In this study, we compare the wear of cups made of X3 crosslinked polyethylene versus traditional polyethyelene. We hypothesize that the X3 crosslinked polyethylene cups have lower wear rates and therefore longer follow-up times.

Study design

Follow-up will be done according to our standard protocol with a visit to the outward clinic at 6 weeks, 6 months, 1 years, 2 year, 3 year, 5 years, 7 years and 10 years. Both clinical data and radiological data will be recorded.

Intervention

At the surgical theatre, patients are randomly assigned into two groups; traditional versus X3 cups. Except for the type of polyethyelene cup, all other parts of the surgery and rehabilitation are equal.

Contacts

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Eligibility criteria

Inclusion criteria

All patients who are younger than 50 years at time of surgery and who are planned for a primary total hip arthroplasty at the department of Orthopaedic Surgery of our University hospital are included.

Exclusion criteria

1. Patients under age of 18 years and older than 50 years;

2. Revision hip arthroplasties.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2010
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-07-2011
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	NL2855
NTR-old	NTR2997
Other	CMO Nijmegen : 2010/206
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A