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

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29039

Bron
NTR

Verkorte titel
X3-trial

Aandoening

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

Ondersteuning

Primaire sponsor: Radboud University Nijmegen Medical Centre, department of Orthopaedics.
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

2. Revision hip arthroplasties.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2010
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-07-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2855
NTR-old	NTR2997
Ander register	CMO Nijmegen : 2010/206
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A