

Wear rate of a Highly Cross-Linked polyethylene stabilized with vitamin E in Total Hip Arthroplasty. A Randomized Controlled Trial.

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The highly cross-linked polyethylene acetabular liner stabilized with Vitamin E has less wear at two years compared with conventional UHMW polyethylene.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23978

Bron

NTR

Verkorte titel

HipVit

Aandoening

highly cross-linked polyethylene
vitamin E
wear rate
Total Hip Arthroplasty

Ondersteuning

Primaire sponsor: Diaconessenhuis Utrecht/Zeist/Doorn

Overige ondersteuning: fund=initiator=sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary final study point is the polyethylene wear rate at 24 months after total hip arthroplasty.

Toelichting onderzoek

Achtergrond van het onderzoek

Wear rate of a Highly Cross-Linked polyethylene stabilized with vitamin E in Total Hip Arthroplasty. A Randomized Controlled Trial.

Doel van het onderzoek

The highly cross-linked polyethylene acetabular liner stabilized with Vitamin E has less wear at two years compared with conventional UHMW polyethylene.

Onderzoeksopzet

Measuring is based on anterior-posterior (AP) radiographs and questionnaires at 3, 12 and 24 months after surgery.

Onderzoeksproduct en/of interventie

Total Hip Arthroplasty will be performed using the RM cementless monoblock pressfit cup (Mathys AG Bettlach) or the RM cementless monoblock pressfitt Vitamys cup (Mathys AG Bettlach). Critical aspects of the surgical procedure will be standardized.

RM Pressfit: RM cementless monoblock pressfit cup is a standard implant.

Structure: Elliptical design and a slight polar flattening.

Polyethylene: UHMW- PE.

Coating material: Pure titanium particles (TiCP).

RM pressfitt Vitamys: RM cementless monoblock pressfit cup stabilized with Vitamin E.

The Vitamys cup is a polyethylene from the same raw material as UHMWPE which has been highly cross linked and additionally endowed with 0.1% of vitamin E, an antioxidant also called tocopherol. The average content of Vitamin E in a Vitamys cup is around 50 mg (max daily amount 400mg) The ingredients are homogeneously mixed, sintered under pressure, and highly cross-linked by an irradiation dose of 100kGy.

Structure: Elliptical design and a slight polar flattening.

Polyethylene: UHMW- PE added with natural anti-oxidant, vitamin E.

Coating material: Pure titanium particles (TiCP).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients scheduled for a total hip arthroplasty;
2. Patients diagnosed for coxarthrosis, dysplastic coxarthrosis, rheumatoid arthritis , necrosis of the head of the femur or posttraumatic coxarthrosis;

3. Patients between 20 and 75 years old at the time of inclusion.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients designated for revision surgery;
2. Suffer from sepsis, malignant tumours, severe diabetes mellitus, severe cardiovascular diseases (ASA>II).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2011
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	26-02-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 34827

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2112
NTR-old	NTR2229
CCMO	NL31682.100.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34827

Resultaten

Samenvatting resultaten

N/A