Wear analysis of cross-linked versus conventional polyethylene acetabulum cups in cemented primary total hip arthroplasty

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It is hypothesized that at 5 year postoperatively, mean annual wear rate in millimetres of the cross-linked polyethylene FAL cups is significantly less compared to the conventional polyethylene FAL cups.

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

Samenvatting

ID

NL-OMON22863

Bron
Nationaal Trial Register

Verkorte titel
FAL cup trial

Aandoening

Total hip arthroplasty
Wear
Cross-linked
Polyethylene

Ondersteuning

Primaire sponsor: Department of Orthopedic surgey, Medical Centre Leeuwarden
Overige ondersteuning: Department of Orthopedic surgery, Medical Centre Leeuwarden. Link Nederland B.V., Schiedam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Mean annual polyethylene wear rate in millimetres at 5 years postoperatively

Toelichting onderzoek

Doel van het onderzoek

It is hypothesized that at 5 year postoperatively, mean annual wear rate in millimetres of the cross-linked polyethylene FAL cups is significantly less compared to the conventional polyethylene FAL cups.

Onderzoeksopzet

Preoperatively and postoperativey at 6 weeks, 3 months, 1 year, 3 years, 5 years and 10 years

Onderzoeksproduct en/of interventie

Patients will receive a crosslinked polyethylene FAL cup® (Link) or a conventional polyethylene FAL cup. The femoral stem will be the SP II® (Link). All surgeons will peform a posterolateral surgical approach. All patients will be treated postoperatively following a standardized protocol.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with

1. age 65- 80 years

2. symptomatic coxartrosis and scheduled for a cemented total hip replacement

3. physical and mentall ability to come for the postoperative follow-up visits

4. written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients with:

1. standard contraindications for total hip replacement, such as infection and severe pulmonary, cardiovascular or metabolic comorbidity

2. neurlogical disorders that affect walking

3. an inability to fill in the questionnaires due to mental or cognitive impairments

4. insufficient understanding of the Dutch language

5. a Body Mass Index > 40

6. an abnormal hip joint anatomy not suitable for the use of the FAL cup and SPII stem

7. an amputation of the lower extremity

8. malignancy receiving anticancer therapy

9. participation in another trial that might interfere with this study

10. an alcolhol or drug dependency

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	20-04-2015
Aantal proefpersonen:	106
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-06-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40132
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6597
NTR-old	NTR6814
CCMO	NL46774.099.13
OMON	NL-OMON40132

Resultaten