Curved versus Straight Stem Uncemented Total Hip Arthroplasty. Osteoarthritis Multicenter trial.

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

Samenvatting

ID

NL-OMON24627

Bron
NTR

Verkorte titel
CUSTOM

Aandoening

Osteoarthritis of the hip
avascular femoral head necrosis
coxarthrose
heup arthose
femurkop necrose

Ondersteuning

Primaire sponsor: Onze Lieve Vrouwe Gasthuis Amsterdam
Oosterpark 9
Postbus 95500
1090 HM Amsterdam
telephone: 0031-(0)20-5999111
Overige ondersteuning: Stichting tot bevordering van deskundigheid in de orthopaedie

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- The Dutch and the German version of the Hip disability and Osteoarthritis Outcome Score (HOOS).

Toelichting onderzoek

Achtergrond van het onderzoek

The purpose of the study is to compare the functional result of CFP stem THA with conventional uncemented straight stem THA, measured by the Dutch or German version of the Hip disability and Osteoarthritis Outcome Score (HOOS) at three months follow-up. The secondary objective will be an evaluation of secondary outcomes. A prospective patient blinded randomized controlled multicentre study.
Straight stemmed total hip arthroplasty involves the insertion of a cementless stem parallel to the longitudinal axis of the femur. Anchorage is on the lateral metaphysic and / or on the diaphysis of the femur. The most commonly used straight stem is the Alloclassic also known as Zweymuller stem (Zimmer, USA). Curved stemmed total hip arthroplasty involves the use of the Collum Femoris Preserving stem (Waldemar Link, Germany). A T.O.P. uncemented acetabular cup (Waldemar Link, Germany) with a polyethylene liner will be used as acetabular component in all cases. Patients will be blinded for the type of prosthesis for the duration of 5 years.

Doel van het onderzoek

Since the CFP stem preserves the insertion of the gluteus muscle on the greater trochanter we expect to find a better short term functional result after CFP stem THA compared to conventional straight stem THA as reflected in higher HOOS scores.

Onderzoeksopzet

• 2 weeks

• 6 weeks

• 3 months (at home)

• 6 months (at home)

• One year

• Annually subsequent 4 years

This results in a total follow-up period of 5 years.

Onderzoeksproduct en/of interventie

Curved Stemmed Total Hip Arthroplasty:

CFP Stem

Uncemented Straight Stemmed Total Hip Arthroplasty

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with disabling osteoarthritis of the hip who are not responding to conservative treatment for at least twelve months, who clinically fulfil the criteria to undergo a cementless total hip arthroplasty.

1. Male or female being 18 years or older

2. Patients meet the criteria for osteoarthritis:

-Pain in one hip

-Arthritic changes on radiograph: joint space narrowing,
femoral / acetabular osteofytes, cysts and signs of sclerosis

3. Patients not responding to conservative therapy

4. Written informed consent for study participation

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients who are mentally impaired and not able to fill out questionnaires

2. Patients who do not know the Dutch or English or German language

3. Patients with a BMI of more than 40

4. Patients with skeletal immaturity

5. Patients with a life expectancy of less than 5 years

6. Patients with altered anatomy resulting in impossibility for the CFP procedure, according to the surgeon e.g.:

-hip dysplasia with high luxation

-post traumatic severe anatomic change

-post-correction osteotomy

7. Patients with lower extremity amputation

8. Patients with an active malignant disease or current cytostatic treatment

9. Patients who are participating in another clinical trial

10. Known alcohol or drug abuse

11. Any condition that would impede measurement of efficacy to the opinion of the surgeon

12. Patients with a previous contralateral hip arthroplasty

13. Patients with contralateral hip pain

14. Avascular head necrosis due to sickelcel anemia

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2009
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-11-2008

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	NL1489
NTR-old	NTR1560
Ander register	: R-08.18O/CUSTOM
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N?A