Primary stability of cemented vs uncemented stems in revision total knee arthroplasty measured with RSA.

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There is no difference in primary stability between cemented and uncemented stems.

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

Samenvatting

ID

NL-OMON27239

Bron
NTR

Verkorte titel
Legion RSA

Aandoening

revision total knee arthroplasty; revisie totale knieprothese; artrose; osteoartritis

Ondersteuning

Primaire sponsor: Sint Maartenskliniek, Nijmegen
Overige ondersteuning: Smith & Nephew

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is the stability of the prosthesis, measured with RSA. Stability is defined as migration (mm) and rotation (degrees) of the tibia and femurcomponent in all degrees of

freedom.

Toelichting onderzoek

Achtergrond van het onderzoek

The number of revision total knee arthroplasties continues to increase annually because of the increased number of primary total knee arthroplasties and the increased age and activity level of the patient. Two methods can be chosen to implant the stems of the prosthesis components into the bone: cemended or press-fit. Up till now, it is not clear which technique yields the most stable result on short and long term. We hypothesize that there is no difference in stability. Which technique, cementing or press-fit implanting, of the tibial and femoral stem of the Legion revision total knee prosthesis provides the most primary stability? The study has been set up as a prospective, blinded, randomised controlled trial. The choice whether the stems will be placed cemented or press-fit will be randomised. For this study 32 patients (16 each group) will be selected. They are on a waiting list for a revision total knee arthroplasty. In patients of the first group the stems of the prosthesis will be cemented, in the other group the stems will be placed press-fit. The primary researchparameter is stability of the prosthesis measured with RSA, expressed in migration of the prosthesis components.

Doel van het onderzoek

There is no difference in primary stability between cemented and uncemented stems.

Onderzoeksopzet

- Pre-operative

- Post-operatief

- after 6 weeks

- after 3 months

- after 6 months

- after 12 months

- after 24 months

Onderzoeksproduct en/of interventie

The trial treatments are cemented or press-fit implantation of the tibial and femoral stems of the Revision total knee arthroplasty and associated hospital preoperative, per-operative and

postoperative standard care, which is identical for both types of treatment.

The cemented treatment will imply fully cementing of the stems of both the tibia and femural component with the use of a cement plug on tibial / femoral side. Third generation cementing technique will be used.

The press-fit implantation technique implies that the distal tibial fixation is provided by a canal filling stem in order to achieve a substantial length of diaphyseal cortical contact.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patient is sceduled for revision total knee arthroplasty.

2. Both cemented and press-fit placed stems are indicated.

3. Patient plans to be available for follow-up through five years post-operative.

4. Patient is in stable health and free of or treated and stabilized for cardiac, pulmonary,

hematological, or other conditions that would pose excessive surgical risk.

5. Patient is willing to consent and participate in the study by signing and dating and IRB-approved consent form.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Radiologically (or per-operatively) defined Type III bone loss according to the Anderson Orthopaedic Research Institute Bone stock Classification.

2. BMI > 35.

3. Acitve, or local infection or systemic infection.

4. Patient has physical, emotional or neurological conditions that would compromise the patient’s compliance with postoperative rehabilitation protocol follow-up (e.g.: drug or alcohol abuse, serious mental illness, or general neurological conditions such as Parkinson, Multiple Sclerosis, etc.).

5. Patient has an immunosuppressive disorder (chronic condition characterized by markedly inhibited ability to respond to antigenic stimuli). Examples of such conditions include patients who are on immunosuppressive therapy (corticosteroid hormones in large amounts, cytotoxic drugs, antilymphocytic serum or irradiation in large doses), patients with acquired immunodeficiency syndrome (AIDS) or auto-immune diseases (including inflammatory arthritis).

6. Patient has a known sensitivity to materials in the device.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2008
Aantal proefpersonen:	32
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-05-2008
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	NL1269
NTR-old	NTR1315
Ander register	Sint Maartenskliniek Research, Development & Education : nr. 289
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A