The role of Cementing on component fixation in Total Knee Arthroplasty using ACS®.

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1. The cemented component tibia performs better than the uncemented tibia component; 2. The uncemented femoral component performs better than the cemented femoral component; 3. The migration of the uncemented femoral component is not altered by…

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

Samenvatting

ID

NL-OMON26032

Bron
NTR

Verkorte titel
LOCKER TRIAL

Aandoening

Arthroplasy, Knee, RSA

Ondersteuning

Primaire sponsor: Stichting Klinisch Wetenschappelijk Onderzoek Slotervaart Ziekenhuis (SKWOSZ)
Overige ondersteuning: Implantcast Benelux

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Migration of the implant using Rontgen Stereophotogrammetric Analysis (RSA).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

For many designs of Knee arthroplasty it remains unsure whether cemented or uncemented fixation of the components has the best long term survival. Many authors even claim that hybrid fixation (uncemented femur and cemented tibia) is the optimal solution.

Objective:

The main objective is measuring the difference in initial migration with means of Rontgen Stereophotogrammetric analysis (RSA) of the different types of fixation. The secondary objective is comparing the QoL and long term survival between groups. The hypothesis is that a cemented tibial plateau and an uncemented femoral component has the least migration.

Study design:

Patient blinded, randomized controlled trial using Rontgen Stereophotogrammetric analysis.

Study population:

The study population will consist of patients with symptomatic osteoarthritis of the knee scheduled for Total Knee Arthroplasty.

Intervention:

Patient in all groups receive an ACS knee arthroplasty, the difference between the groups is the type of fixation of the implant.

Main study parameters/endpoints:

The mains study parameter is the migration of the implants measured with RSA.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

All patient will be seen at regular follow up intervals identical to the normal knee arthroplasty protocol. At these visits a additional RSA X-ray will be made and the patient will be asked to fill out a questionnaire. During the study 5 RSA X-rays per patient will be made, and during 7 follow up visits we will ask the patient to fill in a questionnaire.
All groups consist of treatments that are regularly used, with an implant that is available for more than 10 years and is sold worldwide over 100.000 times. Bearing this in mind we judge the study as safe.

Doel van het onderzoek

1. The cemented component tibia performs better than the uncemented tibia component;

2. The uncemented femoral component performs better than the cemented femoral component;

3. The migration of the uncemented femoral component is not altered by cementing of the tibial component.

Therefore hypothesizing that for the ACS hybrid fixation is the optimal solution.

Onderzoeksopzet

Baseline, direct postoperative, 3 months, 6 months, 1 year, 2 years, 5 years, 10 years.

Onderzoeksproduct en/of interventie

Placement of a cemented, uncemented or Hybrid ACS® knee arthroplasty.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with disabling osteoarthritis and/or destruction of the knee joint scheduled for knee arthoplasy;

2. Patients in the age between 21-80 years;

3. Patients with a BMI<35;

4. Patients in stable health, suitable for surgery, and able to participate in the follow-up program;

5. Patients who signed Written Informed Consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with revision of uni or Total Condylar knee exchange;

2. Patients who are skeletal immature;

3. Patients with Charcot Joints;

4. Patients who have had a patellectomy;

5. Patients who are unable or unwilling to cooperate in follow¬-up program;

6. Patients who have a live expectancy less than 5 years;

7. Patients who are mentally or cognitively disturbed.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	04-03-2013
Aantal proefpersonen:	105
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-03-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47751
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3730
NTR-old	NTR3893
CCMO	NL42872.048.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON47751

Resultaten

Samenvatting resultaten
N/A