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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26032

Source
NTR

Brief title
LOCKER TRIAL

Health condition

Arthroplasy, Knee, RSA

Sponsors and support

Primary sponsor: Stichting Klinisch Wetenschappelijk Onderzoek Slotervaart Ziekenhuis (SKWOSZ)
Source(s) of monetary or material Support: Implantcast Benelux

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Knee disability and Osteoarthrities Outcome Scale (KOOS);

2. Visual Analogue Scale (VAS) for Pain;

3. Short Form (SF) 36;

4. Kujala score.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-03-2013
Enrollment:	105
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-03-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47751
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results
N/A