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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON47751

Source
ToetsingOnline

Brief title
LOCKER TRIAL

Condition

- Bone and joint therapeutic procedures

Synonym
Knee arthroplasty, Knee replacement

Research involving
Human

Sponsors and support

Primary sponsor: Xpert Orthopedie
Source(s) of monetary or material Support: Implantcast

Intervention

Keyword: arthroplasty, cementing, fixation, Knee

Outcome measures

Primary outcome

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

Secondary outcome

The Secondary outcome is the Quality of Life differences and the long term (10

year) follow up regarding revision rates.

Study description

Background summary

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.

Study 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.

Intervention

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

Study burden and risks

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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age 21-80
BMI<35
Symptomatic Osteoarthritis of the knee
In stable health, suitable for surgery and able to participate in follow up.

Exclusion criteria

Charcot Joint
Previous surgery (excluding arthroscopy)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-03-2013
Enrollment:	105
Type:	Actual

Ethics review

Approved WMO

Date:	28-01-2013
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-05-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26032
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL42872.048.12
OMON	NL-OMON26032

Study results

Date completed:	24-08-2020
Actual enrolment:	105