RSA Cohort study

Published: 12-09-2014
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To assess the primary stability of the tibial component of the ACS knee arthroplasty by measuring the migration by use of RSA 2 years postoperatively.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON47870

Source
ToetsingOnline

Brief title
n.a.

Condition

- Joint disorders

Synonym
arthrosis, knee wear

Research involving
Human

Sponsors and support

Primary sponsor: Spaarne Ziekenhuis
Source(s) of monetary or material Support: Implantcast Benelux,industrie

Intervention

Keyword: migration, RSA, Total Knee Arthroplasty

Outcome measures

Primary outcome

The primary outcome is the stability of the prosthesis, measured with RSA.

Stability is defined as migration (mm) and rotation (degrees) of the tibial

component in all degrees of freedom

Secondary outcome

Knee disability and Osteoarthritis Outcome Score (KOOS)

Numerical Rating Scale for pain

SF 12

Migration and rotation at the timepoints postoperatively, 3 months, 6 months

and 12 months postoperatively

Study description

Background summary

The major cause of TKA failure has been shown to be aseptic loosening. The risk of early implant migration depends on different factors like prosthetic design, surface finish and method of fixation. Studies have shown that measuring early micromotions in TKA implantation is usefull for predicting aseptic loosening and the need for revision surgery. The level of early micromotions gives us an important tool for predicting aseptic loosening of the implant.
RSA gives us an accurate measurement of rotation which ranges between 0.15° and 1.15° and between 0.05 and 0.5 mm for translation.

Study objective

To assess the primary stability of the tibial component of the ACS knee arthroplasty by measuring the migration by use of RSA 2 years postoperatively.

Study design

The study design is a single center prospective open label cohort study

assessing the fixation of the tibial component of the ACS TKA design.

Study burden and risks

During and directly after the operation patients will follow the normal protocol for Total Knee Arthroplasty followed by standard outpatient clinic controls at 6 weeks and12 months. The additional burden for patients are;
- additional visits at 3 , 6 and 24 months.
- RSA taken during every visit
- they need to fill out 3 different questionnaires pre- and postoperatively for a total of 5 times.

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

Patients with osteo-arthritis and or destruction of the knee joint
Patients in the age >50 years
Patient is willing to consent and participate in the study by signing and dating an IRB-approved consent form
Patient willing to be available for follow-up evaluations through two years post-operative

Exclusion criteria

Patients who are unable or unwilling to cooperate in follow¬-up program
Patients who are mentally or cognitively disturbed
No written and signed Informed Consent.
Patient with a known sensitivity to materials in the device.
Revision of uni or Total Condylar knee exchange
Skeletal Immaturity
Patellectomy
Active, or local infection or systemic infection

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-08-2015
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	12-09-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-07-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-12-2019
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

No registrations found.

In other registers

Register	ID
CCMO	NL46461.094.13