Comparing the migration and inducible displacement through RSA of the cementless ATTUNETM Rotating Platform and the cementless LCS Rotating Platform Knee system; A Clinical Randomized Controlled RSA follow-up study*

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

Summary

ID

NL-OMON51661

Source
ToetsingOnline

Brief title
ALknee Follow-up Study

Condition

- Joint disorders

Synonym
Total Knee Arthroplasty; Artificial Knee Joint

Research involving
Human

Sponsors and support

Primary sponsor: Spaarne Gasthuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cementless, Inducible replacement, Knee prosthesis, RSA

Outcome measures

Primary outcome

- Migration measured with RSA

Secondary outcome

- Inducible displacement measured with RSA.

- Patient-reported satisfaction is measured by questionnaires.

- Clinical and radiographic outcomes are measured by physical examination and

RSA radiographs.

Study description

Background summary

Every year 1.5 million knee prostheses are implanted worldwide in patients whose knee is severely damaged by osteoarthritis, rheumatism or trauma, resulting in severe pain and loss of function. By 2030, these numbers will have increased sixfold to 7.5 million cases annually due to the aging and increasing population (Kurd et al. 2007). In addition, it is seen that increasingly younger and heavier patients need a knee prosthesis, while they are often still active and, due to their younger age, have to use their prosthesis for a longer period of time. A successfully placed prosthesis reduces pain, restores the function of the joint and functions for at least 10 years, but preferably longer. It is therefore important that new prostheses that come onto the market are improved compared to their predecessors and that these prostheses can be

used for a longer period of time.

Study objective

The primary aim of this study is to accurately compare the mid and long-term migration of two uncemented total knee prostheses. The secondary objectives of this study are to evaluate whether inducible displacement can be used as a parameter to detect implant loosening, and to compare inducible displacement, clinical and radiological outcomes, and patient-reported outcomes after a follow-up of 5 and 10 years of two uncemented knee prostheses: the cementless ATTUNE rotary platform knee prosthesis and the cementless LCS rotary platform knee prosthesis. Both are supplied by DePuy Synthes, Warsaw, Indiana, USA.

Study design

This study is a follow-up to the initial study set up in 2017. (NL58911.058.16) Patients now know what kind of prosthesis they received at the time. Therefore, this study is no longer blind, but a randomized study between the LCS and ATTUNE knee prosthesis.

Study burden and risks

Patients participating in this study will not benefit directly, but the results of this study will improve the understanding of the fixation and performance of cementless prosthesis. This information is very useful in optimizing knee prosthesis designs based on better fixation and better long-term outcomes.

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

- All patients that participated in the initial study (NL58911.058.16)
- Patient that are capable of giving informed consent and expressing a willingness to comply with the study.

Exclusion criteria

- The patient underwent a major revision TKR (exchange of the tibial or femoral component).
- The patient is unable or unwilling to sign the informed consent specific to this study.

Study design

Design

Study phase:	4
Study type:	Observational invasive
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	31-10-2022
Enrollment:	52
Type:	Anticipated

Medical products/devices used

Generic name:	Uncemented ATTUNE knee prosthesis and Prosthesis Cementless LCS prosthesis
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	02-11-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL82000.058.22