A Clinical Randomized Controlled RSA Trial Comparing the Cemented ATTUNE (S+Tibia tray) Fixed Bearing Cruciate Retaining Knee System with the Cemented PFC Sigma Fixed Bearing Cruciate Retaining Knee System

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

Summary

ID

NL-OMON52817

Source
ToetsingOnline

Brief title
RSA RCT: ATTUNE S+ TKA versus Sigma TKA

Condition

- Joint disorders

Synonym
Artificial Knee Joint, Total Knee Arthroplasty

Research involving

Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Depuy International

Intervention

Keyword: Knee Prosthesis, RSA

Outcome measures

Primary outcome

Migration, measured by means of RSA.

Secondary outcome

Patient Reported Outcome Measures by means of questionaires. (PROMS)

Study description

Background summary

Every year, 1.5 million knee prostheses are implanted worldwide in patients whose joints have been severely affected by osteoarthritis, rheumatoid arthritis, or trauma, causing intense pain and loss of function. By 2030 these numbers will have increased six-fold to 7.5 million cases annually, because of our aging and increasingly obese society (Kurtz et al., 2007).
Successful joint replacement surgery provides pain reduction, restores joint function, and will last 10 years at least.

Study objective

The objective of this study is to accurately assess and compare migration, clinical and radiological outcome and patient reported outcomes of two TKR prostheses: the Cemented ATTUNE (S+Tibia component) Fixed Bearing Cruciate Retaining Knee System and the Cemented PFC Sigma Fixed Bearing Cruciate Retaining Knee System, both by DePuy Synthes, Warsaw, Indiana, USA. The primary objective of this study is to compare the magnitude and pattern of migration of the prostheses (Femoral and Tibial component).

Study design

This study is designed as a single-blind, randomized trial between the ATTUNE (S+Tibia component) Knee System and PFC Sigma Knee System. 32 patients with the ATTUNE Knee System and 32 patients with PFC Sigma Knee System will be included in this study.

Intervention

Total Knee replacement Surgery

Study burden and risks

Potential risks are risks associated with normal total knee replacements such as infection, migration, bone loss, pain, loosening of components, thromboembolic complications and risks involving anaesthesia. While the patients participating in this study may not directly derive any immediate benefits, the results of the study should improve the understanding of the fixation and functioning of the prosthesis. This information will be extremely useful in optimising knee implant designs based on better fixation and improved long-term results.

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- 90 years
Indications: Patient is diagnosed with osteoarthritis or rheumatoid arthritis and requiring primary knee arthroplasty
General: All consecutive patients (*usual care*) are included to prevent selection bias in the migration analysis.
Consent: Patient is capable of giving informed consent and expressing a willingness to comply with this study

Exclusion criteria

The patient has an a-priori risk for a posterior-stabilized total knee arthroplasty.
Insufficiency of the posterior cruciate ligament (PCL)
Status after patellectomy
In case flexion is less than 90 degrees
When it is expected that the tibia cut during surgery will compromise the attachment of the PCL (because of
bony defects)
The patient is unable or unwilling to sign the Informed Consent specific to this study
The patient does not understand the Dutch or English language good enough to participate
Patients indicated for revision arthroplasty
When there are not enough markers visible in the baseline RSA photograph and it will not improve by placing
the patient in another position, the patient will be excluded from the study (secondary exclusion criteria).

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2019
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	15-02-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	25-07-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	06-01-2023

Application type:	Amendment
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	NL66908.098.18