Migration and kinematics of the new Persona PS versus the proven NexGen LPS knee - a randomized controlled trial using radiostereometric analysis, fluoroscopy and gait

Published: 02-06-2014
Last updated: 21-12-2024

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

Summary

ID

NL-OMON50724

Source
ToetsingOnline

Brief title
Persona versus NexGen

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
Artificial Knee Joint, Total Knee Artroplasty

Research involving
Human

Sponsors and support

Primary sponsor: Orthopaedie
Source(s) of monetary or material Support: Ministerie van OC&W,Zimmer international.

Intervention

Keyword: CT, Fluoroscopy, Knee Prosthesis, RSA

Outcome measures

Primary outcome

* Migration, measured by means of RSA.

Secondary outcome

* Prosthesis placement and bone resection measured by means of CT and caliper

measurements of the resected bone parts.

* In vivo kinematics by means of fluoroscopy and gait analysis.

* Patient Reported Outcome Measures by means of questionaires.

Study description

Background summary

The NexGen TKR (Zimmer, Warsaw, Indiana, USA) is a proven TKR design that has reported excellent medium and long-term results in clinical studies and in implant registries all around the world. As a follow-up of the NexGen TKR, an improved design has recently been introduced by Zimmer: The Persona TKR (Zimmer, Warsaw, Indiana, USA) has been used successfully in about 20.000 patients, but results from independent clinical studies have not been reported yet.

Study objective

The objective of this study is to accurately assess and compare migration, kinematics, gait analysis, prosthesis placement and patient reported outcomes of two TKR prostheses: the fixed bearing, cemented NexGen LPS, a proven design with an excellent clinical track record, and the fixed bearing, cemented Persona PS, a new design without clinical data (both designs by Zimmer,

Warsaw, Indiana, USA). The primary objective is to assess and compare migration of the two TKR prostheses (Femoral and Tibial component). The secondary objective is to assess and compare clinical data, kinematics, gait analysis, prosthesis placement and patient reported outcome measures.

Study design

This study is designed as a single-blind randomized trial between the Persona PS total knee prosthesis and the well-established NexGen total knee prosthesis.

Different sample sizes are used for the different parts of this study:
* 30 Patients with NexGen LPS prosthesis and 30 patients with Persona PS prosthesis for RSA
* 20 Patients with NexGen LPS prosthesis and 20 patients with Persona PS prosthesis for Gait
* 15 Patients with NexGen LPS prosthesis and 15 patients with Persona PS prosthesis for Fluo

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, tromboembolic complications and risks involving anaesthesia. The NexGen LPS knee has an excellent track record, and the Persona PS knee is considered an improved version of this implant.
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: Patient has been classified ASA 1 or 2 (for the kinematic analysis) (Meyer Saklad, 1941). As for the RSA study all consecutive patients (*usual care*) are included to prevent selection bias in the migration analysis. Stratification is performed per diagnosis group (OA/RA). , Consent: Patient is capable of giving informed consent and expressing a willingness to comply with this study

Exclusion criteria

The patient is unable or unwilling to sign the Informed Consent specific to this study , Insufficient Dutch or English language skills , Patients indicated for revision arthroplasty

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:	Completed
Start date (anticipated):	10-07-2014
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	02-06-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	16-06-2020
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO Date:	06-12-2024
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
ClinicalTrials.gov	NCT02269254
CCMO	NL47243.058.13