Persona Partial Knee - a RSA study

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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-OMON50382

Source
ToetsingOnline

Brief title
PPK RSA study

Condition

- Bone and joint therapeutic procedures

Synonym
knee prosthesis, Knee wear/osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Reinier Haga Orthopedisch Centrum
Source(s) of monetary or material Support: Zimmer Biomet, Warsaw, IN,Zimmer Biomet;Warsaw;IN

Intervention

Keyword: Knee, Persona Partial Knee, RSA, Unicondylar

Outcome measures

Primary outcome

The main study parameter is migration of both the tibial and femoral components of the prosthesis using mRSA, expressed as translations (mm) and rotations (degrees).

Secondary outcome

The secondary objective is to analyze short- and midterm clinical results by means of numeric rating scale (NRS) for pain, range of motion (ROM), Knee injury and Osteoarthritis Outcome Score (KOOS-PS), Oxford Knee Score (OKS), Knee Society Score (KSS) EuroQoL-5D (EQ-5D), radiographic results and satisfaction.

Study description

Background summary

In the Netherlands, 2.053 UKAs were performed in 2014, representing 9% of all knee arthroplasties. The Persona Partial Knee (PKK) is a new unicondylar knee replacement system, with a CE mark. It is of importance to evaluate new prosthesis to know whether the prosthesis is stable. Historically, this was analysed in survival studies, in which loosening was the primairy endpoint. However, these studies lasted long and before the result of the study were known, the prosthesis could be used frequently.
A newer method is Radiosteriometric analysis (RSA) in which the 2-year results seem to be predictive for future loosening of the prosthesis.

RSA is a highly accurate, 3-dimensional method in which migration of the prosthesis in the bone can be measured. It is frequently used in knee prosthesis since the introduction. By using RSA we are able to analyse the stability of the prosthesis. That way, we are able to recognize inferior prostheses.
We would like to evaluate the fixation and migration patterns of the Persona Partial Knee (Zimmer Biomet, Warsaw, IN) using RSA. We hypothesize that the

prosthesis is stable and has minimal translation, micromotion and rotation.

Study objective

The primary objective of this study is to evaluate the fixation and migration patterns of the Persona Partial Knee (Zimmer Biomet, Warsaw, IN) in vivo, using model-based radiostereophotogrammetric (mRSA) analysis.
The secondary objective is to analyze short- and midterm clinical results by means of numeric rating scale (NRS) for pain, range of motion (ROM), Knee injury and Osteoarthritis Outcome Score (KOOS-PS), Oxford Knee Score (OKS), Knee Society Score (KSS) EuroQoL-5D (EQ-5D), radiographic results and satisfaction.

Study design

We will perform a prospective cohort study at the Reinier de Graaf hospital, Delft, the Netherlands. Patients will be recruited from the clinic of the orthopedic department and evaluated preoperatively, at six weeks, six months, one year, two years and five years. The study is expected to start on 01-02-2017 and end on 01-08-2024.

Intervention

Implantation of the Persona Partial Knee prosthesis, manufactured by Zimmer Biomet (Warsaw, IN, USA).

Study burden and risks

Subjects participating in this study have the same risks and benefits when not participating in this study, since the Persona Partial Knee is CE approved and commercially available. 2 additional follow-up moments compared to regulair care are scheduled (on 2 and 5 years after surgery). Furthermore, additional assessments are RSA radiographs and implantation of tantalum marker beads.

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

Specific indications for Persona Partial Knee:* Noninflammatory degenerative joint disease (NIDJD), e.g. osteoarthritis, avascular necrosis
* Traumatic arthritis
* Previous tibial condyle or plateau fractures with loss of anatomy or function
* Varus deformities
* Revision of previous knee surgeries (Although this is an indication for the PPK, patients with previous UKP in the same compartment will not be included in this study. See *2.3 Exclusion criteria*)Subjects must additionally meet the following criteria to participate in this study:
* Age >18 years
* Patient is willing to participate
* Patient is able to speak and write Dutch
* Patient qualifies for UKP based on physical exam and medical history
* Patient is able and willing to provide written informed consent

Exclusion criteria

Subjects will be excluded when they meet one or more of the following contra-indications for the Persona Partial Knee:* Infection, sepsis, and osteomyelitis
* Rheumatoid arthritis or other forms of inflammatory joint disease
* Insufficiency of the collateral, anterior or posterior cruciate ligaments which would preclude stability of the device

* Full thickness damage to the weight bearing area of the contralateral compartment
* Uncooperative patient or patient with neurologic disorders who are incapable of following directions
* Insufficient bone stock to provide adequate support and/or fixation to the prosthesis
* Metabolic disorders which may impair bone formation
* Osteomalacia
* Distant foci of infections which may spread to the implant site
* Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram
* Vascular insufficiency, muscular atrophy, neuromuscular disease
* Incomplete or deficient soft tissue surrounding the knee
* Charcot*s disease
* Fixed varus deformity (not passively correctable) or greater than 15 degrees
* Fixed flexion deformity (not passively correctable) of greater than 15 degrees. Additionally, subjects will be excluded when they meet the following exlusion criteria:* Patient has a known or suspected sensitivity or allergy to one or more of the implant materials
* Revision UKP surgery of the same compartment

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-03-2017
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Persona Partial Knee prosthesis

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	08-02-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	03-11-2020
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

ID: 20822
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL60028.098.16
OMON	NL-OMON20822

Study results

Date completed:	16-06-2023
Actual enrolment:	25