The Persona Partial Knee - an RSA study

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

Summary

ID

NL-OMON20822

Source
Nationaal Trial Register

Brief title
PPK RSA

Condition

- Joint disorders

Synonym
Persona Partial Knee, RSA, Knee, Unicondylar

Research involving
Human

Sponsors and support

Primary sponsor: Zimmer Biomet
Source(s) of monetary or material Support: Zimmer Biomet

Intervention

- Medical device

Explanation

Outcome measures

Primary outcome

Fixation and migration patterns of the PPK prosthesis in vivo, using model-based RSA.

Secondary outcome

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)

• EuroQoL-5D (EQ-5D)

• Radiographs

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

Persona Partial Knee prosthesis

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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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

Indications for PPK prosthesis specifically:

• 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 'Exclusion criteria')

Additional inclusion criteria for 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

Contra-indications for PPK prosthesis specifically:

• 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.

Additional exlusion criteria for this study:

• 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 phase:	N/A
Study type:	Interventional
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-04-2017
Enrollment:	25
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO

Date:	08-02-2017
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

ID: 50382
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6152
NTR-old	NTR6283
Other	METC Zuidwest Holland : 16-131
CCMO	NL60028.098.16
OMON	NL-OMON50382

Study results