A global comparison of Signature Guides and conventional intrumentation in the Oxford partial knee

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Ethical review	Not approved
Status	Will not start
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON38999

Source
ToetsingOnline

Brief title
Signature Oxford UKP in high and low volume

Condition

- Bone and joint therapeutic procedures

Synonym
joint deterioration, osteoarthritis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Oxford UKP, RCT, Signature patient specific guiding

Outcome measures

Primary outcome

Primary Endpoint: To determine the accuracy and precision of Signature Guides

in the Oxford Knee by the percentage of knees achieving optimal alignment

Secondary outcome

Secondary Endpoint: Average Number of Instrument Cases Used

In addition, clinical outcomes and cost efficiency data will be collected to

develop economical models.

Study description

Background summary

Recently, the Signature Custom Guide technology was introduced in total knee arthroplasty. Instead of using an x-ray, the preoperative plan is created by an MRI that is uploaded to a software system so that the surgeon can plan the case preoperatively while seeing the entire knee and leg (not obscured by soft tissue) on their computer screen prior to surgery. Using the planning software, a custom guide is created to align pins used to secure traditional cutting blocks while performing distal femoral and proximal tibial cuts.
By using patient specific guides it is hoped to reduce the number of outliers in placement of the uni knee. Further it is questioned what is the influence of high versus low volume users with this technique.

Study objective

The primary purpose of this study is to compare alignment criteria in the Oxford Partial Knee using conventional instrumentation and Signature Custom Guides.
Secondly it is questioned whether the Signature technology can reduce the number of surgical instruments needed during surgery.
Overall, the intent is to collect the performance and clinical outcomes of the Oxford Partial Knee System using Signature Custom Guides or Conventional

Instrumentation to develop economical models.

Study design

Prospective Multi-Center Randomized Two Armed Trial

Intervention

placement of the unicompartmental knee (Oxford) with Signature (patient specific instrumentation) compared to traditional instruments

Study burden and risks

Because two routine ways to perform Unicompartmental knee replacement with the Oxford are compared and only one additional CT scan is made to objectify the outline of the prosthesis placement is determined, the burden for the patient is limited.

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

- Individuals with osteoarthritis or Avascular necrosis limited to the medial compartment of the knee that is also lacking patellofemoral or lateral compartment disease.
- Patients 21 and over.

Exclusion criteria

- Active Infection, sepsis or osteomyelitis
- Use of prosthesis in lateral compartment of the knee
- Rheumatoid arthritis or other forms of inflammatory joint disease
- revision of failed prosthesis, failed upper tibial osteotomy, or post traumatic arthritis after tibial plateau fracture
- Insufficiency of the collateral, anterior, or posterior cruciate ligaments which would preclude stability of the device.
- Disease or damage to the lateral compartment of the knee
- Uncooperative patient or patient with neurologic disorders who is incapable of following directions
- Poor bone quality / known osteoporosis
- Metabolic disorders (which may impair bone formation)
- Osteomalacia
- Distant foci of infections which may spread to 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
- A fixed varus deformity (not passively correctable) of greater than 15 degrees
- A flexion deformity greater than 15 degrees.
- Non-staged Bilateral patients
- Patients who refuse, cannot, or should not receive a CT or MRI. Since patients are randomized into treatment groups, all patients must be able to receive an MRI (should follow local MRI screening protocol). This excludes patients who have metal artifacts in the knee, patients who are too large to fit into the knee coil, patients with pacemakers, patients unable to lie still for the duration of the MRI, and patients who are claustrophobic.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	22
Type:	Anticipated

Medical products/devices used

Generic name:	Signature
Registration:	No

Ethics review

Not approved

Date:	18-12-2013
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
ClinicalTrials.gov	NCT01763684
CCMO	NL45815.098.13