Onderzoek naar de draaistabiliteit na plaatsing van totale knieprothese met een voorste kruisband besparende versus niet voorste kruisband besparende totale knieprothese

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24201

Source
Nationaal Trial Register

Brief title
ACL, PCL, Bi-cruciate, TKA, Gait analysis

Health condition

Patients who require TKA as a result of gonartrosis

Preservation, ACL, PCL, Bi-cruciate, TKA

Sponsors and support

Primary sponsor: Dep. of Orthopedic Surgery, Atrium-Orbis Medical Centre, location Sittard-Geleen.
Maastricht University, Dep. Human Movement Science
Source(s) of monetary or material Support: NA

Intervention

Outcome measures

Primary outcome

Rotational degrees of freedom of the tibial implant, measured with 3-D motion analysis after operation and compared between the XP tibia implant and CR conventional tibia implant operated with either the MRI-based Signature™ guide or the Conventional alignment

Secondary outcome

•Comparing operative, clinical and radiological outcome of the operative procedure with Signature™ and/or the conventional standard intramedullary alignment guides.

•Verify the fit, form and practical use of the Signature™ alignment guides.

•To determine the occurrence (and percentage) of outliers in alignment in the frontal, sagittal and horizontal plane of femoral and tibial components. Outliers are defined as deviations >3 degrees from preoperative planning.

•To determine the occurrence (and percentage) of outliers in alignment of the mechanical axis of the leg. Outliers are defined as deviations >3 degrees from preoperative planning.

•Verify to what extend the thickness of the in vivo inserted polyethylene corresponds with the pre-operatively calculated thickness of this insert.

Study description

Background summary

The aim of the present prospective randomized clinical trial was to evaluate and compare the rotational laxity and stiffness after TKA with or without preservation of the ACL using 3-D motion analysis for evaluation of rotational biomechanics with the ability to forget the artificial knee joint in everyday life can be achieved as the ultimate goal in joint arthroplasty resulting in the greatest possible patient satisfaction. We hypothesized that preservation of the ACL would result in better rotational stability than TKA without ACL

Study objective

•Bicruciate preserved tibia tray for TKA is at least as efficient and safe as the conventional tibia tray for TKA with elimination of the ACL.
•TKA with the use of Signature™ alignment guide is at least as efficient and safe as TKA with

the use of conventional intramedullary alignment guiding.

Study design

Tibial rotation with Gait motion analysis
• Pre,3 and 6 months and 1 year post operative

Patient Reported Outcome Measures(PROMS)

• Pre,3 M, 6M, 1 Y, 2 Y, 5 Y and 10 Y.

Radiographic evaluation

• Pre,6 W, 1 Y, 5 Y and 10 Y.

Intervention

The Vanguard™ XP total knee system is a cruciate retaining design that allows for the posterior cruciate ligament (PCL) and the anterior cruciate ligament (ACL) to be preserved while incorporating geometry to accommodate and enable the natural function of the ligaments of the knee.
The Vanguard XP implant will be compared with the Vanguard CR implant. The Vanguard™ Complete Knee System features complete interchange ability and multiple sizing options making it the most comprehensive total knee system available, allowing surgeons to provide personalized patient care due to independent fit of the femoral, tibial and patellar components without preservation of the ACL

Contacts

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Eligibility criteria

Inclusion criteria

•Cemented application of components

•Patients with pre-existing contra lateral knee surgery

•Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, or traumatic arthritis where one or more compartments are involved

•Correction of varus, valgus, or posttraumatic deformity

•Sufficient soft tissue surrounding the knee, including the ACL and PCL (based on MRI)

•High need to obtain pain relief and improve function

•Body-mass-index (BMI) <35

•Ability and willingness to follow instructions, including control of weight and activity level, and to return for follow-up evaluations.

•Consent form read, understood and signed by patient.

Exclusion criteria

•Cement less application of components

•BMI greater than or equal to 35

•Use of Anterior Stabilized Bearings or Posterior Stabilized Bearings

•Patients with severe pre-operative varus or valgus deformity greater than or equal to 15 degrees

•Correction or revision of previous joint replacement procedure on index knee

•Sepsis

•Osteomyelitis

•Active infection in knee

•General infection

•Distant foci of infections which may spread to the implant site

•Failure of previous joint replacement

•Pregnancy

•Previous major knee surgery, except for arthroscopic meniscectomy.

•Metal near knee joint (MRI-scan not possible)

•Rheumatoid arthritis

•Extension deficit of more than 15 degrees

•Flexion less than 100 degrees.

•Non-correctable varus axis

•Cruciate ligament insufficiency (based on MRI)

•Rapid joint destruction, marked bone loss, or bone resorption apparent on roentgenogram

•Uncooperative patient or patient with neurological disorders who is incapable of following directions

•Osteoporosis

•Metabolic disorders which may impair bone formation

•Osteomalacia

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-07-2015
Enrollment:	64
Type:	Unknown

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	26-03-2015
Application type:	First submission

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
NTR-new	NL4980
NTR-old	NTR5118
Other	CCMO: NL51534.096.14 : IRB: 14T164

Study results