

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

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•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...

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24201

Bron

NTR

Verkorte titel

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

Aandoening

Patients who require TKA as a result of gonartrosis

Preservation, ACL, PCL, Bi-cruciate, TKA

Ondersteuning

Primaire sponsor: Dep. of Orthopedic Surgery, Atrium-Orbis Medical Centre, location Sittard-Geleen.

Maastricht University, Dep. Human Movement Science

Overige ondersteuning: NA

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

- 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.

Onderzoeksopzet

Tibial rotation with Gait motion analysis

- Pre, 3 and 6 months and 1 year post operative

Patient Reported Outcome Measures (PROMS)

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

Radiographic evaluation

- Pre, 6 W, 1 Y, 5 Y and 10 Y.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Anders
(Verwachte) startdatum:	01-07-2015
Aantal proefpersonen:	64
Type:	Onbekend

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum: 26-03-2015

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4980
NTR-old	NTR5118
Ander register	CCMO: NL51534.096.14 : IRB: 14T164

Resultaten