Tritanium registry

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The uncemented Triathlon Tritanium will provide orthopaedic surgeons a clinically effective alternative to the existing cemented version with all the advantages of cementless fixation, including shorter operating and tourniquet times and possibly...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27668

Bron
NTR

Verkorte titel
Tritanium registry

Aandoening

Osteoarthritis

Ondersteuning

Primaire sponsor: Stryker
Overige ondersteuning: Stryker

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Adverse events/ failures or revision of the Triathlon Tritanium tibia component

Toelichting onderzoek

Achtergrond van het onderzoek

The optimal method of total knee arthroplasty (TKA) fixation remains a challenge. Due to the observed loss of cement-bone interlock due to trabecular resorption, as well as deformation and degradation of the cement mantle over the years, continued attempts have been made to improve the uncemented fixation methods. Uncemented prostheses could in theory increase the biologic fixation due to bone ingrowth, as well as counter bone stock deficiency when a revision is needed. The uncemented Triathlon Tritanium will provide orthopaedic surgeons a clinically effective alternative to the existing cemented version with all the advantages of cementless fixation, including shorter operating and tourniquet times and possibly reduced risk of aseptic loosening due to an improved biological fixation. The aim of this register is to determine the survivorship and performance of the Triathlon Tritanium tibia.

Doel van het onderzoek

The uncemented Triathlon Tritanium will provide orthopaedic surgeons a clinically effective alternative to the existing cemented version with all the advantages of cementless fixation, including shorter operating and tourniquet times and possibly reduced risk of aseptic loosening due to an improved biological fixation.

Onderzoeksopzet

Pre-operative, during hospital stay, 6 weeks, 6 months, 1 year, 2 years and 5 years post-operative

Onderzoeksproduct en/of interventie

uncemented Triathlon Tritanium Tibia

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patient is able to understand the meaning of the study and is willing to sign the EC approved, study specific Informed Patient Consent Form.
2. Patient eligible and scheduled to undergo primary total knee replacement with any of the following indications:
- Painful and disabled knee joint resulting from osteoarthritis (Ahlbäck stage II-V)
- One or more compartments are involved
3. Ability and willingness to follow instructions, including control of weight and activity level and to return for follow-up evaluations.
4. A good nutritional state of the patient.
5. The patient is a male or non-pregnant female between 40 and 75 years of age.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. The patient is morbidly obese, defined as Body Mass Index (BMI) of > 37.
2. Previous major knee surgery.
3. Patient who had a TKA on contralateral side within the last 6 months that is considered to have an unsatisfactory outcome. (Patients with contralateral TKA > 3 months ago with good outcome can be included in the study).
4. Patient with other severe concurrent joint involvements that can affect their outcome.
5. Patient has a flexion contracture of 15 degrees.
6. Patient has a varus/valgus contracture of 15 degrees and more.
7. The patient will be operated bilaterally.
8. The patient has an active or suspected latent infection in or about the knee joint.
9. Osteomyelitis.
10. The patient has a neuromuscular or neurosensory deficiency, which would limit the ability to assess the performance of the device.
11. The patient has a systemic or a metabolic disorder leading to progressive bone deterioration.
12. The patient is immunologically suppressed or receiving steroids in excess of normal

physiological requirements (e.g. > 30 days).
13. Female patients planning a pregnancy during the course of the study.
14. The patient is unable or unwilling to sign the Informed Consent specific to this study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2019
Aantal proefpersonen:	350
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	07-08-2019
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	NL7940
Ander register	METC ZWH : 19-022

Resultaten