Polyethylene wear study on the Triathlon Total Knee Prosthesis: a 10 years follow up RSA study

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21734

Bron
NTR

Verkorte titel
TTK RSA 10 jaar follow up

Aandoening

Osteoarthritis

Ondersteuning

Primaire sponsor: Stryker
Overige ondersteuning: Stryker

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

The Posterior Stabilized (PS) knee prosthesis is the most implanted total knee prosthesis design, but contribute to additional wear debris. Therefore, an alternative bearing surface in total knee replacements was designed to attempt to reduce wear by applying polyethylene in combination with the successful characteristics of a PS knee. Ultra high molecular weight polyethylene (UHMWPE) is nowadays the standard material used for the articulating surface. X3-polyethylene is a new type of polyethylene with improved mechanical properties and theoretically and in vitro improved wear resistance over conventional and current generation cross-linked polyethylene. In a previous study (NL32489.098.10), we compared the wear obtained using Roentgen Stereophotogrammatric Analysis (RSA) and clinical outcomes of the conventional N2Vac with the X3 highly cross-linked polyethylene in a CS fixed bearing total knee prosthesis (Triathlon Knee System: Stryker, Warsaw, USA) during 5 year follow up. However, the time frame of 5 years seems too short to show a significant difference in wear between the groups. Furthermore, we hypothesize that stronger inserts (X3) might induce small partical wear resulting in loosening of the prosthesis. In this study, we will assess the in vivo wear of the two randomized polyethylene insert types N2Vac and X3 and the migration and long-term survival of the Triathlon CS Peri-Apatite coated titbial component 10 years after surgery.

Doel van het onderzoek

We expect that the X3-polyethylene has animproved wear resistance over conventional and current generation cross-linked polyethylene (N2Vac).This material should theoretically lead to superior wear characteristics and consequently long-term durability and survivorship of the prosthesis.
Furthermore, we expect that the stronger insert (X3) might induce small partical wear, which might further lead to earlier loosening of the prosthesis compared to the N2Vac inlay.

Onderzoeksopzet

10 years post-operative

Onderzoeksproduct en/of interventie

1. N2Vac inlay
2. X3 inlay
Both combined with a CS fixed bearing total knee prosthesis (Triathlon Knee System: Stryker, Warsaw, USA)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Received a Total Knee Joint prosthesis between September 2011 and May 2014;
- Participated in the study assessing the mid-term wear of the N2Vac or X3 insert;
- Sign informed consent of the proposed study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- The patient was withdrawn from the previous study;
- Revision/Removal of study device;
- Patient withdrawal on patients own request;
- Lost to Follow-Up;
- Death of the patient;
- The patient is unable or unwilling to sign the Informed Consent specific to this study.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2021
Aantal proefpersonen:	87
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:	30-06-2021
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	NL9579
Ander register	METC LDD : P21.056

Resultaten