Polyethylene Wear of the N2Vac and X3 insert in the Triathlon Total Knee Prosthesis: 10 years follow up of a prospective Randomized Single Centre RSA study

Published: 08-07-2021
Last updated: 04-07-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON50837

Source
ToetsingOnline

Brief title
Triathlon Total Knee Prosthesis RSA 10 years follow up

Condition

- Bone and joint therapeutic procedures

Synonym
degenerative joint disease, osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Reinier Haga Orthopedisch Centrum
Source(s) of monetary or material Support: Stryker,Stryker Howmedica

Intervention

Keyword: Polyethylene insert, Roentgen Stereophotogrammatric Analysis (RSA), Total Knee Arthroplasty, Wear

Outcome measures

Primary outcome

The main study endpoint is the in-vivo wear in mm of the N2Vac insert compared

to the wear of the X3 insert, 10 years after surgery.

Secondary outcome

Secondary endpoints are migration and long-term survival of the Triathlon CS

Peri-Apatite coated tibial component, clinical scores and radiographic

aspects.Clinical scores are expressed by the scores of the following

questionnaires: the Knee Society Score (KSS), EQ-5D-3L, SF-36 and

Lower-Extremities Activity Scale (LEAS).

Study description

Background summary

Total knee arthroplasty is commonly used to treat osteoarthritis. 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 resulting in the CR knee prosthesis. 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.

Study objective

The primary objective is to assess the in vivo wear of the two randomized polyethylene insert types N2Vac and X3 10 years after surgery. The secondary objective is to assess the migration and long-term survival of the Triathlon CS Peri-Apatite coated tibial component and to assess the clinical scores and radiographic aspects 10 years after surgery.

Study design

This study is a cohort study, describing the 10 year-follow up after implantation of the CS fixed bearing total knee prosthesis in combination with a N2Vac or X3 insert, which was part of a prospective randomized single center study (NL32489.098.10, METC 10-068). Radiostereometric analysis (RSA) will be used to determine the wear of both inserts.

Study burden and risks

There are no benefits for patients in this study. RSA radiographs will be made once and patients will be asked to visit once the outpatient clinic and fill in questionnaires.

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

- 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.

Exclusion criteria

- 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.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-10-2021
Enrollment:	87
Type:	Actual

Ethics review

Approved WMO

Date:	08-07-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	23-08-2021
Application type:	Amendment
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
CCMO	NL77360.058.21