Triathlon Tritanium Tibia Registery; national multicentre surveillance register

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To verify the uncemented Triathlon Tritanium Knee System safety during follow-up and survivorship as described by Kaplan-Meier survival curves.To document the patient clinical outcome of the patients who have received an uncemented knee arthroplasty...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON52880

Source
ToetsingOnline

Brief title
Triathlon Tritanium Tibia Registery

Condition

- Joint disorders

Synonym
Knee osteoarthritis, knee wear and tear

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Knee, Triathlon Tritanium knee system, Uncemented

Outcome measures

Primary outcome

All adverse events / failures or revision of the Triathlon Tritanium tibia

component

Secondary outcome

Standard clinical parameters (knee society score, KSS) and PROMs (Oxford Knee

Score (OKS), Knee Inury and Osteoarthritis Outcome Score (KOOS), Forgotten

Joint Score (FJS), EuroQol 5D (EQ5D) and Hospital Anxiety Depression Scale

(HADS))

Study description

Background summary

Total knee systems consist of a femoral and tibital component with a tibial baseplate to enhance rotation and flexion. The Triathlon Tritanium knee system is an uncemented knee system. Tritanium is highly porous metal biologic fixation technology. improving biological fixation as the three-dimensional highly porous titanium surface aids bone ingrowth. It is expected to have similar or even better results concerning early fixation properties and long-term durability compared to cemented and HA-coated fixation.

The uncemented Triathlon Tritanium is not a new design. The articulating geometry of the components is identical to the cemented version, as is the operative technique (obviously, besides the method of fixation) and postoperative regime. 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.

Study objective

To verify the uncemented Triathlon Tritanium Knee System safety during follow-up and survivorship as described by Kaplan-Meier survival curves.

To document the patient clinical outcome of the patients who have received an uncemented knee arthroplasty surgery involving a Triathlon Tritanium tibia component.

Study design

National multicentre, prospective follow-up of a consecutive series of patients eligible for a knee arthroplasty surgery

Intervention

Implantation of the Triathlon Tritanium Knee System

Study burden and risks

The use of the Triathlon Tritanium Knee System will not increase the risks compared with the standard used knee system. There are no experimental procedures. Participation in this study will not affect the medical treatment of enrolled patients.

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

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.

Exclusion criteria

1. The patient is morbidly obese, defined as Body Mass Index (BMI) of > 37.
2. Previous major knee surgery.
3. Patient who had a Total Knee Arthroplasty (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.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-08-2020
Enrollment:	350
Type:	Actual

Medical products/devices used

Generic name:	Triathlon Tritanium Knee System
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	31-07-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	16-08-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	06-10-2022
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	NL66250.098.19