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All-polyethylene tibia PS components compared to metal-backed tibia PS components in total knee replacement

Submission date
22/09/2014

Recruitment status
No longer recruiting

Registration date
26/11/2014

Overall study status
Ongoing

Last Edited
05/12/2023

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Metal-backed total knee replacements are the most commonly used total knee replacements all over the world. However, knee replacements with all-polyethylene tibial components remain an attractive alternative as they are cheaper and avoid problems such as the knee joint mechanism locking and some wear and tear issues. Here, we want to compare two types of total knee replacements – the Triathlon PS Knee System with all-polyethylene tibial components and the Triathlon PS Knee System with metal-backed modular tibial components.

Who can participate?
Adults aged 40 to 75 who need a total knee replacement.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 receive the all-polyethylene tibial components for their total knee replacement. Those in group 2 receive the metal-backed modular tibial components for their total knee replacement. The two types of knee replacements are then compared using RSA (radiostereometric analysis) X rays. This is a special technique that takes two X-rays of the joint from different angles at the same time. This creates a 3D image that can be viewed. During surgery, tiny beads are placed in the bone that will surround the knee replacement. These beads are then used to check the positioning of the knee replacement and whether that changes over time. Each patient taking part in the study is invited to a number of follow up visits – one before being discharged from hospital, one 3 months after surgery, and then at 1, 2, 5, 7 and 10 years after surgery. During these visits, they are asked to complete questionnaires about their health, their activities and their knee. RSA X-rays are also taken.

What are the possible benefits and risks of participating?
The study will help increase knowledge of the two knee replacement systems used in the study.

Where is the study run?
Hässleholms sjukhus, Hässleholm (Sweden)

When is the study starting and how long is it expected to run for?
October 2014 to December 2025

Who is funding the study?
Stryker European Operations BV (Netherlands)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
K-S-046

Study information

Scientific Title
Migration and survival of all-polyethylene tibial components compared to the metal-backed modular components of the Triathlon PS Total Knee System. A RSA study

Acronym
N/A

Study objectives
1. The primary objective is the assessment of prosthetic migration results after two years with the Triathlon PS Knee System with all-polyethylene tibial components compared to the Triathlon PS Knee System with metal-backed modular components by means of Roentgen Stereophotogrammetry.
2. The secondary objective will be the prediction of the long-term survival based on the two-year migration patterns combined with clinical factors and radiographic aspects. In order to identify other clinical parameters besides the fixation of the prosthesis components, clinical scores and radiographic aspects will be correlated with the RSA outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Ethical Review Board in Lund, Sweden, 02/09/2014, ref. Dnr 2014/513

Study design
Single-center randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Osteoarthritis

Interventions

Patients are informed and screened pre-operative. Patients that comply with the inclusion /exclusion criteria and who give their consent for participation will be given a study ID. After signing Informed Consent, the patients will be randomized in one of the two groups, the day before surgery. The patient will receive either the all-polyethylene tibial component or the metal backed modular tibial component for their Triathlon PS total knee. The principal investigator and the participating surgeons may dissent from the randomization scheme based on intra-operative findings. This patient will be excluded from the study. Follow-up visits are performed at the following time points: prior to discharge, 3 months, 1, 2, 5, 7 and 10 years after surgery. During these visits clinical evaluation and x-rays are done, any adverse events are monitored (if applicable) and the KOOS, EQ-5D and FJS questionnaires are completed by the patient.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
All-polyethylene PS Triathlon Total Knee System, Metal-backed PS Triathlon Total Knee System

Primary outcome measure
The primary outcome measure will be prosthetic migration after two years of the Triathlon PS Knee System with all-polyethylene tibial components and the Triathlon PS Knee System with metal backed modular components by means of Roentgen Stereophotogrammetry.
It is hypothesized that there will be no difference between groups. The difference in migration between components must not exceed 0.3 mm for translations and 0.25° for the rotations to determine equivalence

Secondary outcome measures
The secondary outcome measure will be long-term survival based on the two-year migration patterns combined with clinical factors and radiographic aspects. In order to identify other clinical parameters besides the fixation of the prosthesis components, clinical scores and radiographic aspects will be correlated with the RSA outcome. The 10-year results will be used to verify the predicted long-term survival results.

Overall study start date
10/09/2014

Completion date
31/12/2025

Eligibility

Key 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. Patients with a pre-operative knee score of < 70
3. Patients scheduled to undergo primary total knee replacement with any of the following indication
3.1. Painful and disabled knee joint resulting from osteoarthritis
3.2. One or more compartments are involved
4. No indication for Triathlon PS
5. Need to obtain pain relief and improve function
6. Ability and willingness to follow instructions, including control of weight and activity level, and to return for follow-up evaluations
7. A good nutritional state of the patient
8. The subject is a male or non-pregnant female between 40 and 75 years of age

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
1. The subject is morbidly obese, defined as Body Mass Index (BMI) of > 40
2. Patient has a flexion contracture of 15° and more
3. Patient has a varus/valgus contracture of 15° and more
4. Patients with a pre-operative knee score of >70
5. The subject has a history of total or unicompartmental reconstruction of the affected joint
6. The subject will be operated bilaterally
7. Patients who had a Total Hip Arthroplasty (THA) on contralateral and/or ipsilateral side within the last year that is considered to have an unsatisfactory outcome (Patients with contralateral and/or ipsilateral THA > 1 year ago with good outcome can be included in the study)
8. Patients 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 > 6 months ago with good outcome can be included in the study)
9. The subject has an active or suspected latent infection in or about the knee joint
10. Osteomyelitis
11. Sepsis
12. Patient who is expected to need lower limb joint replacement for another joint within one year
13. The subject has a neuromuscular or neurosensory deficiency, which would limit the ability to assess the performance of the device
14. The subject has a systemic or metabolic disorder leading to progressive bone deterioration
15. The subject is immunologically suppressed or receiving steroids in excess of normal physiological requirements
16. The subjects bone stock in compromised by disease or infection which cannot provide

adequate support and/or fixation to the prosthesis
17. The subject has had a knee fusion to the affected joint
18. Female patients planning a pregnancy during the course of the study
19. The patient is unable or unwilling to sign the Informed Consent specific to this study

Date of first enrolment
10/09/2014

Date of final enrolment
30/04/2015

Locations

Countries of recruitment
Sweden

Study participating centre
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Sponsor information

Organisation
Stryker European Operations BV (Netherlands)

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Stryker European Operations BV (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	2-year results	25/09/2019	05/12/2023	Yes	No
Results article	5-year results	24/01/2022	05/12/2023	Yes	No