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Polyethylene wear study on the triathlon total knee prosthesis

Submission date
11/03/2014

Recruitment status
No longer recruiting

Registration date
31/03/2014

Overall study status
Completed

Last Edited
23/05/2022

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
A knee implant consists of two metal parts with a plastic (polyethylene) bearing part in between. The aim of the study is to assess the differences between two types of bearings regarding fixation and wear. The first type, N2Vac, is commonly used and has excellent results. The other type, X3, is a newer generation and is expected to produce even better results

Who can participate?
Patients who undergo primary total knee replacement

What does the study involve?
Participants will be randomly allocated to one of two groups: N2Vac group or X3 group. Fixation and wear is measured by X-rays (RSA (röntgen stereophotogrammetric analysis RSA). To be able to do these measurements, a number of tantalum beads (1mm diameter) will be placed in the bone surrounding the prosthesis during the knee surgery and one extra X-ray will be taken during each follow-up.

What are the possible benefits and risks of participating?
The study involves the routine assessment of a knee arthroplasty procedure. The devices are CE marked and will be used according to their labelling. The study will help increase knowledge. Participants will be invited for one extra visit compared to the routine procedure. During each visit the patient will be asked to complete questionnaires about their health, their activities and their knee and one additional RSA X-ray will be taken (the radiation dose falls within acceptable limits).

Where is the study run?
Langeland Hospital, Zoetermeer, the Netherlands

When is the study starting and how long is it expected to run for?
The study started in September 2011 and the last enrolment was in June 2014. The study is expected to close in June 2019.

Who is funding the study?
Stryker European Operations BV

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT02525588

Protocol serial number
K-S-039

Study information

Scientific Title
Polyethylene wear study on the triathlon total knee prosthesis: a prospective randomized single centre study

Study objectives
1. The primary objective is the assessment of the in vivo wear of the two randomized polyethylene inlay types N2Vac and X3 by means of Roentgen Stereophotogrammetry. It is expected that the X3 group will show significantly less wear after 5 years compared to the conventional N2Vac polyethylene group.
2. The secondary objective is the assessment of prosthetic migration results after two years of the Triathlon CS Peri-Apatite coated tibial and femoral components by means of Roentgen Stereophotogrammetry. It is expected that due to the superior wear qualities of X3 polyethylene this group will show significantly less migration of the prosthesis components after two-years compared to the components in the N2Vac group.
3. The third objective will be the prediction of the long-term survival of the Triathlon CS Peri-Apatite coated tibial and femoral components based on the two-year migration patterns combined with clinical factors and radiographic aspects. In order to identify other clinical parameters besides wear influencing the fixation of the prosthesis components, clinical scores

and radiographic aspects will be correlated with the RSA outcome. Subsequently, a long-term prediction can be for the Triathlon CS Peri-Apatite coated tibial and femoral components.

Ethics approval required
Old ethics approval format

Ethics approval(s)
METC Zuidwest Holland, 28/04/2011

Study design
Single-center randomized controlled trial (RCT)

Primary study design
Interventional

Study type(s)
Treatment

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. During surgery, the randomization envelope with the corresponding study ID is opened. This envelope prescribes the type of insert (N2Vac or X3) to be used. The label sticker of the implant that is used is kept on the randomization log in the Investigator site file. The investigator site file is kept at a different location than where the follow-up visits and RSA X-ray analyses are performed.

Follow-up visits are performed at the following time points: prior to discharge, 6 weeks, 3 months, 6 months, 1, 2 and 5 years after surgery. During these visits x rays are done, any adverse events are monitored (if applicable) and the LEA, EQ-5D and SF-36 questionnaires are completed by the patient. Furthermore standard X-rays, as well as one additional RSA X-ray are taken.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Assessment of the in vivo wear of the two randomized polyethylene inlay types N2Vac and X3 by means of Roentgen Stereophotogrammetry. It is expected that the X3 group will show significantly less wear after 5 years compared to the conventional N2Vac polyethylene group.

Key secondary outcome(s))
Assessment of prosthetic migration results after two years of the Triathlon CS Peri-Apatite coated tibial and femoral components by means of Roentgen Stereophotogrammetry. It is

expected that due to the superior wear qualities of X3 polyethylene this group will show significantly less migration of the prosthesis components after two-years compared to the components in the N2Vac group.

Completion date
30/06/2019

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. Need to obtain pain relief and improve function.
5. Ability and willingness to follow instructions, including control of weight and activity level, and to return for follow-up evaluations.
6. A good nutritional state of the patient.
7. Full skeletal maturity of the patient, patients who are at least 18 years of age.
8. Patients of either sex.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. The subject is morbidly obese, defined as Body Mass Index (BMI) of > 40.
2. Skeletal immaturity of the patient, patients who are less than 18 years of age.
3. Patient has a flexion contracture of 15° and more.
4. Patient has a varus/valgus contracture of 15° and more.
5. Patients with a pre-operative knee score of >70.
6. The subject has a history of total or unicompartmental reconstruction of the affected joint.
7. The subject will be operated bilaterally.
8. 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).

9. 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).
10. The subject has an active or suspected latent infection in or about the knee joint
11. Osteomyelitis
12. Sepsis
13. Patients who will need lower limb joint replacement for another joint within one year.
14. The subject has a neuromuscular or neurosensory deficiency, which would limit the ability to assess the performance of the device.
15. The subject has a systemic or metabolic disorder leading to progressive bone deterioration.
16. The subject is immunologically suppressed or receiving steroids in excess of normal physiological requirements.
17. The subjects bone stock in compromised by disease or infection which cannot provide adequate support and/or fixation to the prosthesis.
18. The subject has had a knee fusion to the affected joint.
19. Female patients planning a pregnancy during the course of the study.
20. The patient is unable or unwilling to sign the Informed Consent specific to this study.

Date of first enrolment
30/09/2011

Date of final enrolment
01/06/2014

Locations

Countries of recruitment
Netherlands

Study participating centre
Langeland Hospital
Zoetermeer
Netherlands
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Sponsor information

Organisation
Stryker European Operations BV (Netherlands)

ROR
https://ror.org/02nwyam20

Funder(s)

Funder type
Industry

Funder Name
Stryker European Operations BV

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		07/04/2020	23/05/2022	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes