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The ATX registry

Submission date
20/07/2012

Recruitment status
No longer recruiting

Registration date
17/08/2012

Overall study status
Completed

Last Edited
05/01/2017

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Total hip replacement is one of the most common and successful techniques used in orthopaedic surgery. Along with cemented hip replacements, cementless hip replacement has proven its value. Still, the survival of hip implants is not indefinite. Over the years knowledge on stability, fixation and preservation of bone stock has increased considerably. Better understanding of joint movement also allow us to design implants with reduced joint reaction forces, which again may lead to improved survival of implants. The Stryker Accolade™ Femoral Component is a relatively new hip system constructed from a beta titanium alloy (TMZF®). The alloy, which can offer greater flexibility and higher tensile strength than standard titanium alloys, has an elasticity modulus (stiffness) that is closer to that of bone. The upper half of the stem is coated with a hydroxyapatite (HA) coating, which assists in bone ingrowth and provides a good interface for fixation of the stem. The Accolade II stem is an evolution of the Accolade TMZF stem. The size-specific fit of the stem has been redesigned to fit a broad range of bones sizes and shapes found in todays patient population. The aim of this study is to determine the safety and survivorship of the Accolade/Accolade II stem and the Trident/Tritanium cup over 10 years and to document the patients clinical outcome and satisfaction.

Who can participate?
All patients eligible for a hip arthroplasty surgery involving the Accolade or Accolade II stem and Trident or Tritanium cup who have been informed about this surveillance register and who freely consent to participate.

What does the study involve?
The study involves the routine assessment of a hip arthroplasty procedure. Patients who participate in the study will be invited for routine visits and during each visit the patient will be asked to complete one questionnaire about their health and one about their activities and their hip. Follow-ups take place at 1, 3, 5, 7 and 10 years after the surgery.

What are the possible benefits and risks of participating?
Patient benefits should include relief of pain and increase in functional capabilities, in addition to better assessment of the effect of prosthesis design and materials on functional and radiographic performance and bone remodelling around cementless femoral prostheses. This will increase the current scientific body of knowledge concerning total hip arthroplasty. As with any surgical procedure, certain risks are associated with total joint arthroplasty. These risks

include but are not limited to: anaesthetic and post-anaesthetic reactions (such as hyperaemia), allergic reactions to prophylactic antibiotics or blood transfusions, damage to blood vessels or nerves, trochanteric or femoral fractures during implantation, perforation of the cortical wall, or death. After the operation, a patient may experience thrombophlebitis, pulmonary embolus, dislocation, pain, limp, component loosening, osteolysis due to wear debris or the need for additional surgery. Fracture of the prosthesis is a potential complication. Pre-clinical, clinical and mechanical testing of the Stryker Accolade and Accolade II Hip Stem and Trident/Tritanium cup indicate that the above mentioned risks should not occur at a rate greater than that of any other type of total hip arthroplasty reported in the literature.

Where is the study run from?
1. Amphia ziekenhuis Breda, Netherlands
2. Ziekenhuis Netwerk Antwerpen, Merksem, Belgium
3. Orbis Medisch Concern Sittard, Netherlands
4. St. Antoniusziekenhuis, Utrecht, Netherlands
5. Rijnstate ziekenhuis Arnhem/Zevenaar, Netherlands
6. Ikazia ziekenhuis Rotterdam, Netherlands
7. Skånevård Kryh, Hässleholm, Sweden
8. Harrogate District Hospital, Harrogate, UK

When is the study starting and how long is it expected to run for?
February 2012 to June 2025

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

Who is the main contact?
Sietske Witvoet

Contact information

Type(s)
Scientific

Contact name
Dr Stefan Bolder

Contact details
Location Molengracht Orthopedie
Postbus 90158
Breda
Netherlands
4800

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT02520544

Secondary identifying numbers
ATX20120712

Study information

Scientific Title
The ATX registry - accolade stem & Trident/Tritanium cup with X3 insert international multicentre surveillance register

Acronym
ATX

Study objectives
1. Clinical outcome is as good as or better than published results of other press-fit stems
2. Similar clinical results can be obtained with non-designer surgeons as compared to the designer surgeons
3. Tapered stems perform well in all patient populations

Ethics approval required
Old ethics approval format

Ethics approval(s)
ETC-AMPHIA Ethics Committee, 20/06/2011, ref: BW/niet WMO nr.080.11

Study design
Prospective international multicentre surveillance register

Primary study design
Observational

Secondary study design
Prospective international multicentre surveillance register

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/hip joint

Interventions

No comparative treatments here. This is a follow-up register of one cohort of patients undergoing total hip arthroplasty. Follow-ups are due at 1, 3, 5, 7 and 10 years

Intervention Type
Device

Primary outcome measure
1. To verify the Accolade/Accolade II stem and Trident/Tritanium cup safety during follow-up and survivorship as described by Kaplan-Meier survival curves
2. To document the patient clinical outcome of the patients who are eligible for a hip arthroplasty surgery involving an Accolade/Accolade II stem and Trident/Tritanium cup

Secondary outcome measures
1. All intra-operative and post-operative adverse events
2. Standard clinical parameters
3. Harris Hip Score, registered preoperatively and at each follow-up visit
4. Oxford Hip Score, registered preoperatively and at each follow-up visit
5. EQ5D, registered preoperatively and at each follow-up visit

Overall study start date
01/02/2012

Completion date
30/06/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 26/08/2014:
1. Male and non-pregnant female patients between 18-75 years of age
2. Patients requiring uncemented primary THA, suitable for the use of the Accolade stem and Trident/Tritanium cup
3. Patients with a diagnosis of osteoarthritis (OA)
4. Patients who understand the conditions of the study and are willing and able to comply with the post-operative scheduled clinical and radiographic evaluations and the prescribed rehabilitation
5. Patients who signed the Ethics Committee approved Informed Consent Form prior to surgery

Previous inclusion criteria:
1. Male and non-pregnant female patients between 18-70 years of age
2. Patients requiring uncemented primary THA, suitable for the use of the Accolade stem and Trident/Tritanium cup
3. Patients with a diagnosis of osteoarthritis (OA)
4. Patients who understand the conditions of the study and are willing and able to comply with the post-operative scheduled clinical and radiographic evaluations and the prescribed rehabilitation
5. Patients who signed the Ethics Committee approved Informed Consent Form prior to surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
478

Key exclusion criteria
1. Patients who require revision of a previously implanted hip prosthesis
2. Patients who had a THA on contralateral side within the last 6 months
3. Patients who had a THA on contralateral side more than 6 months ago and the rehabilitation period outcome was considered unsatisfactory or not good (Harris Hip Score < 85)
4. Patients who will need lower limb joint replacement for another joint within one year
5. Patients requiring bilateral hip replacement
6. Patients who have had a prior procedure of acetabular osteotomy
7. Patients with acute femoral fractures
8. Obese patients where obesity is severe enough to affect subjects ability to perform activities of daily living (body mass index, kg/m2: BMI ≥ 35)
9. Patients with active or suspected infection
10. Patients with malignancy active malignancy
11. Patients with severe osteoporosis, rheumatoid arthritis (RA), Pagets disease or renal osteodystrophy
12. Patients immunologically suppressed, or receiving steroids in excess of physiologic dose requirements
13. The patient has a neuromuscular or neurosensory deficit which would limit their ability to assess the performance of the device or the patient has a neurological deficit which interferes with the patients ability to limit weight bearing or place an extreme load on the implant during the healing period
14. Female patients planning a pregnancy during the course of the study
15. Patients with systemic or metabolic disorders leading to progressive bone deterioration
16. Patients, who as judged by the surgeon, are mentally incompetent or are unlikely to be compliant with the prescribed post-operative routine and follow-up evaluation schedule
17. Patients with other severe concurrent joint involvements, which can affect their outcome
18. Patients with other concurrent illnesses, which are likely to affect their outcome such as sickle cell anaemia, systemic lupus erythematosus or renal disease requiring dialysis
19. Patient with a known sensitivity to device materials
20. Patients under the protection of law (e.g. guardianship)

Date of first enrolment
01/02/2012

Date of final enrolment

28/02/2015

Locations

Countries of recruitment
Belgium

England

Netherlands

Sweden

United Kingdom

Study participating centre
Amphia ziekenhuis Breda
Netherlands
-

Study participating centre
Ziekenhuis Netwerk Antwerpen
Merksem
Belgium
-

Study participating centre
Orbis Medisch Concern Sittard
Netherlands
-

Study participating centre
St. Antoniusziekenhuis
Utrecht
Netherlands
-

Study participating centre
Rijnstate ziekenhuis Arnhem/Zevenaar
Netherlands
-

Study participating centre
Ikazia ziekenhuis Rotterdam
Netherlands
-

Study participating centre
Skånevård Kryh
Hässleholm
Sweden
-

Study participating centre
Harrogate District Hospital
Harrogate
United Kingdom
HG2 7SX

Sponsor information

Organisation
Stryker European Operations BV (Netherlands)

Sponsor details
Herikerbergweg 110
Amsterdam
Netherlands
1101 CM

Sponsor type
Industry

Website
http://www.stryker.com/

ROR
https://ror.org/02nwyam20

Funder(s)

Funder type
Industry

Funder Name
Stryker SA (Switzerland)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available