Prospective register-based study of Trident II - SHAR

Background: Hip replacement is regarded as a successful intervention in treating patients with degenerative hip disorders. Although advances have been made in hip replacement surgery, approximately 10% of all patients operated with primary hip replacement will undergo further surgical interventions during their life-time. The risk of revision due to loosening is unevenly distributed between ages and increases with decreasing age. Manufacturers are trying to improve implant design to further reduce the risk of implant failure. Further implant manufacturers need to update the production line replacing the outdated facilities.
The Trident II cup (Stryker Orthopaedics, Mahwah, NJ) represents a new manufacturing technology. So far, its clinical documentation in the primary total hip arthroplasty is promising but limited. Therefore, clinical documentation in a prospective multicentre study with careful monitoring is necessary before a wider introduction.

Purpose of the present study and design: In a prospective register-based study, we aim to evaluate the implant survival, clinical outcomes and X-ray findings by following a cohort of patients operated with the Trident II cup. Our primary outcome will be implant survival at 3 years. Our secondary outcomes will be:

- Implant migration measured with Computer Tomography Micro-motion Analysis (CTMA) in a sub-cohort of patients
- Implant survival at 10 years
- Patient-reported outcomes (EQ-5D, OHS and FJS) at 1, 6, and 10 years
- Plain radiographs in a sub-cohort of patients
- Adverse events using the national patient register – needs separate approval process
- Adverse events using the regional VEGA database – needs separate approval process

Study design
Number of hips in the study: 500. 250 cases of Trident II Hemispherical (Stryker Orthopaedics) and 250 Trident II Tritanium (Stryker Orthopaedics) respectively. Following high volume centres have been invited to participate in the study:

- Sahlgrenska/Mölndal
- Borås and Skene
- Västerås
- Lidköping
- Linköping
- Visby
- Ängelholm?
- Karolinska/Huddinge
- Torsby

Methods:

Power analysis:

Determine if there is evidence of inferiority as per benchmarking recommendations by The Orthopaedic Data Evaluation Panel (ODEP). ODEP criteria includes:

- A minimum cohort of 150 hips at the start of the study (consisting of data from beyond the developing centre and from more than 3 centres/surgeons) with a minimum of three years follow up and an actual revision rate of less than 3%
- A minimum cohort of 250 hips/knees at the start of the study (consisting of data from beyond the developing centre and from more than 3 centres/surgeons) with a minimum of five years follow up and an actual revision rate of less than 5%
- A minimum cohort of 500 hips at the start of the study (consisting of data from beyond the developing centre and from more than 3 centres/surgeons) with a minimum of ten years follow up and an actual revision rate of less than 5%

Inclusion criteria

1. Age: 30 to 75 years
2. Eligible for uncemented fixation on the acetabular side
3. Suitable for one of the stem designs from Stryker Orthopaedics
4. Accepts follow-up according to the study protocol
5. Primary hip replacement

Exclusion criteria

1. Difficulties to understand written information due to language problems or other reasons
2. Use of augments needed
3. Acute hip fracture
4. Tumor in the hip joint

The study will be nested within the Swedish Hip Arthroplasty Register. Clinical parameters will be collected using a web/paper form incorporated in the register.

A. Clinical parameters: EQ-5D, Oxford Hip Score and Forgotten Joint Score are filled in by the patients. Clinical parameters will be studied preoperative after 1, 6 and 10 years.

B. Conventional radiography: Examinations will be done preoperatively, postoperatively, 2, 6 and 10 years after total hip replacement.

C. CTMA will be done postoperatively, 3 and 6 month and 2 years after total hip replacement

Reporting: A first scientific report, including all primary and secondary data, will be provided as a manuscript when all patients for every cohort have been followed for 3 years.

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