ISRCTN81577353 https://doi.org/10.1186/ISRCTN81577353

Clinical study comparing cementless Polar stem and the cementless Corail stem in total hip replacement

Submission date
06/03/2012

Recruitment status
No longer recruiting

Registration date
21/03/2012

Overall study status
Completed

Last Edited
09/08/2021

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
A total hip replacement (THR) is used in the treatment of severe and debilitating arthritis of the hip; the natural, arthritic ball and socket joint is removed and replaced with an artificial prosthesis, or implant.
A THR implant (also known as prosthesis) comes in four pieces; a stem, a head, a liner and a cup. These all fit together; the head and the liner form the ball and socket part of the joint. The head sits on the stem, and the liner fits in the cup. The stem sits inside the thigh-bone (femur) and the cup sits in the pelvic bone. It is important in THR that the stem and the cup are well fixed in place and do not move within the bone. This type of movement, referred to as migration, is linked with early to mid-term failure of the implant, and can require re-operation. The orthopaedic manufacturer De Puy developed a stem called the 'Corail', which has been shown to have minimal migration, and is the most commonly used implant in THR. It has two versions, one with a collar and one without. It is not known whether the presence of the collar helps prevent excessive migration. This has led to the development of the 'Polar' stem by the orthopaedic manufacturer Smith & Nephew, which is similar in design to the Corail, but has not been directly compared in performance to the Corail. The first aim of this study is to assess the relative migration of the Polar and the Corail stems over a 2-year period in THR to see whether the Polar performs comparably or even better than the Corail. The second aim is the comparison of migration of the cementless R3 cup with a well-established cementless comparison by using radiostereometric analysis (RSA). This study has been designed to document the migration of the implants over 2 years via x-ray analysis and clinical outcomes.

Who can participate?
Patients aged 50-75 who have a diagnosis of debilitating hip arthritis and require THR

What does the study involve?
The study involves a radiostereometric analysis (RSA) x-ray, which is a widely used method of measuring implant movements. It involves the insertion of 1-mm spherical tantalum markers around the prosthesis and x-rays being taken at intervals to show any change in relative position. These metallic markers are easy to identify on x-rays, do not cause a reaction in the body and

have no known side-effects. Participants undergo THR with one of three possible hip arthroplasty stems: the Corail collared stem, the Corail collarless stem or the Polar stem, and the tantalum markers are inserted at the time of surgery. RSA is then used as part of routine follow-up after the operation, to measure any migration of the stem.

What are the possible benefits and risks of participating?
The benefits may include identifying a superior prosthesis in terms of migration, resumption of high levels of function and overall patient satisfaction. There are risks associated with THR surgery. However, all implants used in the study have the CE mark, and are used routinely in many hospitals by many surgeons. There are no additional risks associated with participating in this study in comparison to an identical patient receiving an identical THR. The tantalum metallic markers do not cause a reaction in the body and have no known side-effects. There are no extra burdens associated with the study, as patients will return for clinical and RSA follow-up at 6 weeks, 6 months, 1 and 2 years after the operation, identical to those patients who are not in the study.

Where is the study run from?
University College Hospital NHS Foundation Trust (UK)

When is study starting and how long is it expected to run for?
July 2012 to July 2015

Who is funding the study?
The study is part funded by Smith and Nephew Orthopaedic, who developed the Polar THR

Who is the main contact?
Prof. Fares Haddad

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A prospective, randomised, single centre clinical study comparing cementless Polar stem and the cementless Corail stem in total hip replacement

Study objectives
The null hypothesis is that there is no difference in migration rates of the Corail or Polar stems at 2 years.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London – City Road and Hampstead, 17/06/2015, ref: 15/LO/0661

Study design
Prospective randomised single-centre clinical study

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
Hip osteoarthritis, total hip replacement

Interventions
The 75 patients recruited to the study will be randomly allocated to one of 3 groups:
1. Polar stem + R3 cup
2. Corail collarless + Pinnacle cup
3. Corail collared + Pinnacle cup

Each patient will have a 1:3 chance of receiving either the Polar stem and R3 cup, the Coral collarless stem and Pinnacle cup or the Corail collared stem and Pinnacle cup; they will not be

aware of the prosthesis they have received until the end of the study. Although it is possible to randomise and blind the prosthesis to the patient and the Researcher gathering outcome data, it is not possible to blind the surgeon on the day of surgery.

Surgery will be performed and routine post-operative care provided, which includes rehabilitation and safe discharge from hospital. Each particicpant, regardless of each treatment arm, will receive identical care. A post-operative Radiostereometric Analysis (RSA) xray will be performed prior to discharge, and each participant will then be seen at 6 weeks, 6 months, 1 and 2 years post-op for RSA images and clinical follow-up.

Intervention Type
Procedure/Surgery

Primary outcome measure
Comparison of migration of the cementless Polar stem (Smith & Nephew Orthopaedics) with a well established cementless collarless and collared comparison stem (Corail, DePuy Orthopedics) in THR, by using RSA

Secondary outcome measures
1. Comparison of migration of the cementless R3 cup (Smith & Nephew Orthopaedics) with a well established cementless comparison (Pinnacle, DePuy Orthopedics) by using RSA
2. Documenting the performance of the Polar and Corail implants in the clinical setting over two years post-operatively, using information on infection and complication rates and specific Health Related Quality of Life (HRQoL) outcome/satisfaction scores to see whether there is any difference in performance

Overall study start date
01/07/2012

Completion date
01/07/2020

Eligibility

Key inclusion criteria
1. The surgeon and the patient must agree that total hip replacement (THR) is necessary
2. The patient must be fit for THR in the opinion of the surgeon and the interdisciplinary team
3. The indication for THR must be primary osteoarthritis, avascular necrosis, femoral neck fracture, or hip dysplasia
4. Patients requiring primary arthroplasty
5. Patients must be aged between 50 - 75 years at the time of surgery
6. Both male and female
7. The patient must be capable of giving informed consent and express a willingness to comply with the post-operative review program
8. The patient must be a permanent resident in an area accessible to the study site

Participant type(s)
Patient

Age group

Mixed

Sex
Both

Target number of participants
75

Key exclusion criteria
1. Post-traumatic OA (proximal femur fracture)
2. Post-infection in respective joint
3. Prior osteotomy of the affected hip
4. Patients under treatment for osteoporosis (with bisphosphonate)
5. OA patients diagnosed Charnley Classification
6. Patients requiring cortisone medication
7. Patients whose body mass index is higher than 35
8. Patients already participating in the RSA hip study.
9. The individual is unable or unwilling to sign the patient informed consent specific to this study
10. Previous THR on contra-lateral side
11. Patients requiring revision arthroplasty

Date of first enrolment
02/11/2015

Date of final enrolment
01/07/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London Hospital
London
United Kingdom
NW1 2PG

Sponsor information

Organisation
Joint UCL / UCLH / Royal Free Biomedical Research Unit (UK)

Sponsor details
Ground Floor, Rosenheim Wing
25 Grafton Way
London
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Sponsor type
Research council

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Industry

Funder Name
Smith & Nephew Orthopaedics (UK)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal with intent to publish at or around one-year post trial end date.

Intention to publish date
01/12/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No