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Surveillance of hip replacements using radiostereometric analysis

Submission date
04/11/2014

Recruitment status
No longer recruiting

Registration date
27/11/2014

Overall study status
Completed

Last Edited
08/08/2022

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
The replacement of painful arthritic joints with artificial implants is a highly successful and cost-effective means of addressing pain and disability. Hip replacements are particularly effective, but it is known that many of them fail after around 15-20 years. The National Joint Register of England and Wales contains information from all hip replacement operations performed in the UK and this shows that there is a 5-20% risk of needing further surgery 10 years after a hip replacement. There are many reasons for the implant failing; these include fracture of the bone around the replacement, dislocation and infection. The most common reason is gradual loosening over time of the implant. Research has shown that the stability of the implant in the bone within the first 2 years after the surgery is of vital importance. Measuring the stability of the implant in this early period is therefore a proven method for gauging the success of the implant and how long it is likely to last. The stability of an implant refers to the motion of the prosthesis in relation to the surrounding bone. It has been shown in multiple studies that early migration (movement) of an implant over the first 2-years after surgery is predictive of late failure. Radiostereometric analysis (RSA) has been widely used in many applications particularly in the assessment of stability of joint replacements. It is a highly accurate, three-dimensional method of looking at the movement between an implant and the host bone. It involves placing 1mm spherical metal markers in the bone around the implants, radiographic examinations, and the subsequent calculation of three-dimensional movements. The metal used for the markers is called tantalum and is an element with a high atomic number and is therefore easy to identify on radiographs. It is biologically inert, and been used as a bone marker material for this purpose without any known side-effects. Its use is particularly widespread in the Netherlands and Scandinavian countries where RSA data is mandatory for the release of new implants to the market. Here, we want to compare the stability of two hip replacement stems (TriFit femoral stem or the POLARSTEM) in the first 2-years after transplantation using RSA. This will allow us to predict which implant we would expect to last the longest and which design is most favourable.

Who can participate?
Adult patients, aged 18-80 that need a total hip replacement.

What does the study involve?
Participants are randomly allocated to receive either the the TriFit femoral stem (investigation

group) or the POLARSTEM (control group). Both stems are used in patients suffering from pain and disability arising from hip joint arthritis that need to be treated with a hip replacement. The implant designs are based on the principle of achieving stability without the need of cement. They achieve this by both having a specially designed coating which encourages the patient's bone to grow on to the implant and hold it tightly. These implants are also designed for this hold to take place in the top part of the thigh bone (femur) to maximise the strength of the patient's own bone and to limit taking away too much of the patient's bone. RSA is used to assess how much the implant has moved in relation to the host bone for both types of implant at regular time intervals.

What are the possible benefits and risks of participating?
This study will be of benefit to individual patients as well as to the wider orthopaedic community. Detailed analysis of implant stability will be possible for those enrolled in the study. Although we anticipate that this will improve patient care this has not been definitively shown and so RSA is not currently part of routine practice. This additional information will help guide clinicians, for example, to see if persistent pain suffered by a patient is due to the implant becoming loose. Furthermore, this information will provide vital data on the optimum design of implant to ensure it lasts as long as possible. No side-effects or adverse events have been reported from the use of the tantalum marker beads or from participation in an RSA study. There will be only minor inconvenience as initially more time will be required to take the specialist radiographs however this should quickly reduce with experience. There is a theoretical risk from the radiation required for the additional x-rays however these images require extremely low doses of radiation as the beads are very dense and readily show up on the x-ray. It has been estimated that enrollment in an RSA study carries the same additional radiation exposure as is experience from a year's background radiation of daily living.

Where is the study run from?
University College London Hospital (UCLH) (UK)

When is the study starting and how long is it expected to run for?
January 2015 to December 2018

Who is funding the study?
Corin Ltd (UK)

Who is the main contact?
Professor Fares Haddad

Contact information

Type(s)
Scientific

Contact name
Prof Fares Haddad

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
v 1.0

Study information

Scientific Title
A prospective, randomised, single centre clinical study comparing stability of the cementless TriFit femoral stem versus the cementless POLARSTEM by radiostereometric analysis

Acronym
N/A

Study objectives
The study has been designed as a non-inferiority study.
H0: Total migration in the investigation group (TriFit) after the first 2 postoperative years is substantially more compared to the migration in the control group (POLARSTEM).
H1: Total migration in the study group after the first 2 postoperative years is equal or less than in the control group.

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 controlled single centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Degenerative conditions of the hip requiring joint replacement

Interventions
This study is a prospective, single centre, randomised controlled study. Patients will be randomly allocated to one of 2 treatment groups: the 'investigation' group will receive the TriFit cementless femoral stem, and the 'control' group the POLARSTEM cementless femoral stem. Research participants include any patient requiring a total hip replacement for any cause e.g. osteoarthritis, inflammatory arthritis, developmental dysplasia, trauma. For randomisation purposes an on-line random number generator program (www.random.org) will be accessed. A number from 1 to 100 can be randomly generated and will allocate a patient to one of the arms of the study: 1-50 inclusive for the control group, 51-100 inclusive for the investigation group.

The study will be conducted in a single clinical centre (UCLH), with up to 60 patients enrolled in a 1:1 ratio between the two treatment groups. Up to 60 patients should be enrolled to ensure that 50 patients are followed for the duration of the study. The enrolment goal is to have at least 25 patients in each of the two treatment groups completing the study. Patients will be recruited if they meet all of the inclusion criteria and none of the exclusion criteria. It is anticipated that enrollment will take up to 2 years, therefore for each patient to be followed up for 2 years the study will be completed within 4 years.

The time-line for the study is as follows. Once a patient is identified who satisfies all of the inclusion criteria for the study and none of the exclusion criteria they will be given a local ethics committee approved information leaflet and invited to participate in the study. The research team will be available to answer any questions at this time and in the period leading up to the day of surgery. On the morning of their operation they will be asked to sign the separate study consent form and any further questions answered. Their operation will be identical to normal with the exception of the placement of approximately 8 metal beads around the implant.

Post-operatively the patient will be seen as per the departmental protocol with follow-up at 2 weeks, 6 weeks, 6 months, 1 year and 2 years post-operatively. Standard follow-up radiographs will be taken at each of these time-points with additional radiostereometric images taken also at each visit. Clinical assessment and functional scores will be taken post-operatively, these include: Harris Hip Score, Oxford Hip Score, EQ5D.

Intervention Type
Procedure/Surgery

Primary outcome measure
The primary endpoint of the study is the migration of the prosthesis at 2 years post-implantation by means of Radiostereometric Analysis (RSA). This will be measured using model-based RSA (MBRSA) methods with calculation of the overall translation and rotation of the implant at regular time-points.

Secondary outcome measures
The secondary endpoints of the study are:
1. Pattern of migration of the TriFit vs. POLARSTEM: baseline to 2-year post-procedure.

2. Assessment of micromotion (inducible displacement) at 6 weeks and 1 year post-implantation for TriFit vs POLARSTEM.
3. For both stems: Harris Hip Score, Oxford Hip Score and EQ5D pre-operatively, 6 months, 1 year and 2 years post-operatively
4. For both stems: Analysis of standard antero-posterior and lateral plain film radiographs taken post-operatively, 6 weeks, 6 months, 1 year and 2 years post-operatively
5. Incidence of adverse device effects and adverse events.

Overall study start date
01/01/2015

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. The surgeon and the patient must agree that primary total hip replacement (THR) is necessary
2. The patient must be fit for the operation in the opinion of the surgeon and the interdisciplinary team
3. The indication for primary THR must be primary osteoarthritis, avascular necrosis, femoral neck fracture, hip dysplasia, inflammatory arthritis
4. Patients requiring primary arthroplasty only
5. The TriFit / POLARSTEM implant is an acceptable choice of implant to match the patients anatomy (confirmed with acetate / digital templating)
6. Patients must be aged between 18 80 years at the time of surgery
7. Sex: both male and female
8. The patient must be capable of giving informed consent and express a willingness to comply with the post-operative review program
9. The patient must be a permanent resident in an area accessible to the study site
10. The patient must have sufficient post-operative mobility to attend follow-up clinics and allow for radiographs to be taken

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
There will be a total of 60 participants with 30 randomly allocated to each study arm.

Key exclusion criteria

1. Patient not suitable for primary joint replacement e.g. requires arthrodesis (fusion) or revision (re-do) surgery
2. Patient not fit for surgery
3. Underlying cause for osteoarthritis separate from that included in inclusion criteria e.g. suspected infection, osteoporosis, osteomyelitis
4. Patient younger than 18 years old or older than 80 years old
5. Patient already enrolled in a clinical trial including other radiostereometric analysis study
6. Post infection in affected hip
7. Severe deformity in femur prohibiting the use of the proximally fitting implant
8. The individual is unable or unwilling to sign the patient informed consent specific to this study
9. Anticipated that the patient will lack sufficient mobility to attend follow up at Institute of Sport, Exercise and Health (ISEH)
10. Patient non-resident in local area or expected to leave catchment area post-operatively

Date of first enrolment
01/01/2015

Date of final enrolment
03/09/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Sport, Exercise and Health (University College London)
London
United Kingdom
NW1 2BU

Sponsor information

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

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Industry

Funder Name
Corin Ltd (UK)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

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