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A randomised, prospective, single blind study comparing a standard metal on polyethylene cemented socket in primary hip replacement versus an uncemented ceramic on ceramic bearing socket in patients under 65 years old

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
04/03/2016

Condition category
Surgery

[ ] 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 hip replacement is a common type of surgery where a damaged hip joint is replaced with an artificial one. The aim of this study is to determine the most appropriate type of hip replacement to be used in the younger, higher demand patient undergoing total hip replacement.

Who can participate?
Patients aged under 65 undergoing primary total hip replacement.

What does the study involve?
Participants are randomly allocated to receive one of two types of hip replacement: either an uncemented ceramic-on-ceramic bearing socket or a standard metal-on-polyethylene cemented socket. Revision rates are then compared between the two groups (i.e., does one group have to have their hip replacements re-done either earlier or more frequently than the other).

What are the possible benefits and risks of participating?
If a significant benefit is found in one group compared to the other, this practice could be adopted across the Hip Unit in primary total hip replacement in patients under 65 years old.

Where is the study run from?
The Princess Elizabeth Orthopaedic Centre (UK)

When is the study starting and how long is it expected to run for?
March 2005 to March 2020

Who is funding the study?
1. Royal Devon and Exeter NHS Trust (UK)
2. NHS R&D Support Funding (UK)

Who is the main contact?
John Timperley

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

Protocol serial number
N0203162871

Study information

Scientific Title
A randomised, prospective, single blind study comparing a standard metal on polyethylene cemented socket in primary hip replacement versus an uncemented ceramic on ceramic bearing socket in patients under 65 years old

Study objectives
Which is the optimum bearing surface for hip replacements in the younger, high demand patient- metal on polyethyene or ceramic on ceramic? The aim of the study is to provide an evidence base regarding the most appropriate type of hip replacement to be used in the younger, higher demand patient undergoing total hip replacement. If significant benefit is found in one arm of the trial compared to the other, this practice would be adopted across the Hip Unit in primary THR in patients under 65 years old.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design

Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Surgery: Hip replacement

Interventions
A randomised, prospective, blinded clinical trial is to be set up to compare the effect of an uncemented ceramic on ceramic bearing versus a cemented socket with a metal on polyethylene articulation in primary total hip replacement in patients under 65 years old. The study will be carried out in both the wards and out-patient clinics of the Princess Elizabeth Orthopaedic Centre. Patients will be approached at the pre-assessment clinic and offered the opportunity to be involved in the research. Surgeons will consent the patients re this study. Informed written consent to partake will be mandatory for inclusion and any patient who declines will be excluded. Patients who agree to enter the study will be divided at random to enter different arms of the study. 161 patients to be initially included into each group with allocation to either arm of the trial by drawing appropriately marked slips of paper from an opaque envelope. The surgeon will not be able to read the slips before they are drawn. Various outcome measures will be used including the need for re-operation for any reason, development of osteolysis, development of aseptic cup loosening, component failure, dislocation, Oxford and Harris hip scores and the modified Charnley scoring system.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
Comparison of revision rates ie does one group have to have their hip replacements re-done either earlier or more frequently than the other.

Key secondary outcome(s))
Not provided at time of registration

Completion date
16/03/2020

Eligibility

Key inclusion criteria
Any patient admitted by the Hip Unit surgeons about to undergo primary total hip replacement, aged under 65 and who has given informed consent to take part

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Age > 65
2. No informed consent

Date of first enrolment
17/03/2005

Date of final enrolment
16/03/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Devon & Exeter Hospital (Wonford)
Exeter
United Kingdom
EX2 5DW

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Devon and Exeter NHS Trust (UK)

Funder Name
NHS R&D Support Funding (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes