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Improving the bearing surface in total hip replacement (THR): the use of oxidised zirconium and highly cross-linked polyethylene

Submission date	Recruitment status	[X] Prospectively registered
21/03/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/04/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/05/2016	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
04/Q0505/71

Study information

Scientific Title

Improving the bearing surface in total hip replacement (THR): the use of oxidised zirconium and highly cross-linked polyethylene - a randomised controlled trial

Study objectives
Does the use of oxidised zirconium femoral heads in total hip replacement reduce the rate of volumetric and linear wear as compared to conventional material heads, whilst providing comparable outcome measures?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Joint UCL/UCLH Committees on the Ethics of Human Research (Committee A), 14/01/2005, ref: 04/Q0505/71

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Arthritis of the hip

Interventions
Primary total hip replacement, using either cobalt chrome or oxinium femoral heads and either standard or highly cross-linked polyethylene liners.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Radiographic wear; measuring linear & volumetric wear based on standardised AP & lateral radiographs of the pelvis then analysed with an automated edge detection technique

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

Completion date
01/09/2009

Eligibility

Key inclusion criteria
1. The patient and surgeon agree that primary THR is necessary
2. The patient is 18 years of age or older (either sex) on the day of signing the Study Consent

Form
3. The patient is capable of participating in the study:
3.1. Fluent in English, or has a capable proxy
3.2. Mentally intact
3.3. Emotionally stable
3.4. A permanent resident in an area accessible to the study site

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Current medical conditions such as:
1.1. Metastatic or primary tumor of the hip
1.2. Implantation into a previously resected hip (i.e. conversion to THR)
1.3. Neurologic deficit impairing the affected limb
2. History of medical conditions such as:
2.1. Septic arthritis in the affected hip
2.2. Reflex sympathetic dystrophy of the affected leg
2.3. Progressive muscular condition causing deterioration of the abductor muscles
2.4. Hip pain associated with back pathology such as spinal stenosis or vascular occlusion

Date of first enrolment
14/01/2009

Date of final enrolment
01/09/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Princess Grace Hospital
London

United Kingdom
W1U 5NY

Sponsor information

Organisation
University College London Hospitals NHS Trust (UK)

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Industry

Funder Name
Smith & Nephew (UK) - discretionary grant to fund salary of MD student only

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?
Results article	results	01/07/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes