

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

Submission date 21/03/2005	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/04/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/05/2016	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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 below to request a patient information sheet

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 measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date

14/01/2009

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

200

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

England

United Kingdom

Study participating centre

Princess Grace Hospital

London

United Kingdom

W1U 5NY

Sponsor information

Organisation

University College London Hospitals NHS Trust (UK)

Sponsor details

The Middlesex Hospital

Mortimer Street

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England

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W1T 3AA

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Sponsor type

University/education

Website

<http://www.uclh.nhs.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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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