

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

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

**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?
<a href="#">Results article</a>	results	01/07/2015		Yes	No