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# Assessment of bone remodeling by dual energy X-ray absorptiometry after cemented total hip replacement: a prospective randomized study comparing three different designs

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| **Submission date**<br>30/09/2004 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>30/09/2004 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>14/11/2014 | **Condition category**<br>Surgery | [_] Individual participant data<br>[_] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N0209132499

# Study information

## Scientific Title

## Study objectives
1. How is bone remodelled around the cemented femoral head of three different designs of hip: triple tapered collarless (C Stems), double tapered collarless stems (TPS) and collared stems (Stanmore)?
2. To what extent do each type tend to conserve bone stock?

## 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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied
Surgery: Total hip replacement

## Interventions
Patients will be randomised to receive one of the three types of hip:
1. Triple tapered collarless (C Stems)
2. Double tapered collarless stems (TPS)
3. Collared stems (Stanmore)

Pre-surgery, blood will be analysed for vitamin D, parathyroidhormone, and bone profile assay will be performed. Dual X-ray absorptiometry (DEXA) will be done preoperatively than at 3-5 days post-op, and at 3, 6, 12 and 24 months post-op.

## Intervention Type

Procedure/Surgery

**Phase**
Not Applicable

**Primary outcome measure**
Is there any difference between the bone loss secondary to bone remodelling in each type of hip?

**Secondary outcome measures**
Not provided at time of registration

**Overall study start date**
01/04/2003

**Completion date**
01/06/2005

# Eligibility

**Key inclusion criteria**
60 patients undergoing primary total hip replacement

**Participant type(s)**
Patient

**Age group**
Not Specified

**Sex**
Not Specified

**Target number of participants**
60

**Key exclusion criteria**
Not provided at time of registration

**Date of first enrolment**
01/04/2003

**Date of final enrolment**
01/06/2005

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Royal National Orthopaedic Hospital**
Stanmore
United Kingdom
HA7 4LP

# Sponsor information

**Organisation**
Department of Health

**Sponsor details**
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

**Sponsor type**
Government

**Website**
http://www.dh.gov.uk/Home/fs/en

# Funder(s)

**Funder type**
Government

**Funder Name**
Royal National Orthopaedic Hospital NHS Trust (UK)

# 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