ISRCTN43978921 https://doi.org/10.1186/ISRCTN43978921

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

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