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

Registration date
30/09/2004

Overall study status
Completed

Last Edited
14/11/2014

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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

Protocol serial number
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

Study type(s)
Treatment

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(s)
Is there any difference between the bone loss secondary to bone remodelling in each type of hip?

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

Completion date
01/06/2005

Eligibility

Key inclusion criteria
60 patients undergoing primary total hip replacement

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Royal National Orthopaedic Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration