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Comparison of washed and unwashed allograft in revision hip replacement

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 22/09/2014	**Condition category** Surgery	

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
N0203096531

Study information

Scientific Title

Study objectives
Does the use of washed morcellised allograft in revision surgery of the femoral component of a total hip replacement improve the clinical or radiological result when compared with the use of unwashed material?

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: revision hip replacement

Interventions
Initial patient selection followed by consent to be included in trial. Randomisation by sealed envelope in theatre when condition of femur established and operative procedure decided upon. Tantalum balls to be inserted into femur. Adapted radiostereometric analysis (RSA) Exeter stems and distal plugs to be implanted.
Beads to be inserted in cement and in graft. Post-op RSA and plain X-rays. Routine Exeter post-op mobilization protocol to be followed. Routine follow-up at 6 weeks, 6 months, 1 year and then yearly for 5 years (this is the routine follow-up protocol). RSA films to be taken at each appointment. Routine standard anteroposterior (A-P) films to be taken bi-annually. Dual energy X-ray absortiometry (DEXA) scan to be repeated at each routine post-op appointment until completion of trial.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
To conduct a randomised trial to study the effect of washing the allograft bone used in impaction grafting at revision hip arthroplasty. Patients undergoing revision hip surgery will be randomised into two groups at the time of their operation. An identical surgical procedure will be carried out except that one group will have the morcellised allograft washed and the other group will have unwashed graft used as is the present practice. The patients will be followed up for 5 years.

Outcome measures include complications, clinical scores, bone healing as quantified on DEXA scanning and gross radiological appearances. In addition, movement of the construct at each interface will be assessed by the technique of RSA.

Study end points: life tables and survival curves with confidence limits for different definitions of failure including implant loosening and radiological evidence of failure including implant migration (as defined by RSA), excessive wear, radiolucencies, etc. Log rank comparison.

Secondary outcome measures
Not provided at time of registration

Overall study start date
04/06/2001

Completion date
30/06/2006

Eligibility

Key inclusion criteria
1. Patients requiring revision hip arthroplasty for aseptic femoral component loosening
2. Age less than 85
3. Femoral bone stock loss equivalent to Endoklinik 2 or 3 (loss of cancellous bone in the proximal femur, possible parosteal increase in dimension but essentially a cavitary defect only with no need for reconstruction meshes or long stems).

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
04/06/2001

Date of final enrolment
30/06/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Devon & Exeter Hospital (Wonford)
Exeter, Devon
United Kingdom
EX2 5BW

Sponsor information

Organisation
Department of Health (UK)

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

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Royal Devon and Exeter 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