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A randomised controlled trial to assess the effect of bone graft extender added to 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 13/10/2017	**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
N0203114901

Study information

Scientific Title
A randomised controlled trial to assess the effect of bone graft extender added to allograft in revision hip replacement

Study objectives
Does the addition of bone graft extender material to morcellised allograft in revision surgery of the femoral or acetabular component of a total hip replacement improve the clinical or radiological result when compared to allograft alone?

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
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
A randomised prospective clinical trial is to be set up to test the efficacy of bone graft extenders in comparison with 100% allograft (to study the effect of the addition of a synthetic bone graft extender material to allograft bone used in impaction grafting at revision hip arthroplasty). Patients who fulfill the entry criteria will be randomized into two groups: one group will have the morcellised bone for their reconstruction mixed with bone graft extender in a 50:50 ratio, and the other group will not. The patients will be followed up for 5 years.
Twelve patients to be initially included into each arm of the trial. The numbers needed for the study have been calculated from previous discussions with Dr Greco at the RDSU regarding a

project with similar endpoints and expectation outcomes. Based on the analysis of operating schedules over a 12 month period (July 2000-2001), 40 patients were identified who would have been considered as suitable for inclusion in this study.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Outcome measures include complications, clinical scores and gross radiological appearances. In addition movement of the construct at each interface will be assessed by the technique of Radio Stereometric Analysis (RSA).

Study endpoints: 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
30/08/2002

Completion date
29/08/2007

Eligibility

Key inclusion criteria
1. Patients requiring revision hip arthroplasty for aseptic femoral or acebular component loosening.
2. Age less then 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). Therapeutic research.

Participant type(s)
Patient

Age group
Senior

Sex
Not Specified

Target number of participants
40

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
30/08/2002

Date of final enrolment
29/08/2007

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

Hospital/treatment centre

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