

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 13/10/2017	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Mr John Timperley

### Contact details

Royal Devon & Exeter Hospital (Wonford)  
Barrack Road  
Exeter, Devon  
United Kingdom  
EX2 5BW

## Additional identifiers

### Protocol serial number

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

## **Study type(s)**

Treatment

## **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(s)**

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.

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

29/08/2007

**Eligibility****Key inclusion criteria**

1. Patients requiring revision hip arthroplasty for aseptic femoral or acetabular 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 cavitory defect only with no need for reconstruction meshes or long stems). Therapeutic research.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

Not Specified

**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**

United Kingdom

England

**Study participating centre**

**Royal Devon & Exeter Hospital (Wonford)**

Exeter, Devon  
United Kingdom  
EX2 5BW

## Sponsor information

**Organisation**

Department of Health (UK)

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Royal Devon and Exeter NHS Trust (UK)

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration