

# A randomised, controlled trial assessing the effectiveness of the iliac suction device in improving socket fixation in primary hip arthroplasty

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 13/10/2017	<b>Condition category</b> Surgery	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**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**  
N0203114899

## Study information

**Scientific Title**

A randomised, controlled trial assessing the effectiveness of the iliac suction device in improving socket fixation in primary hip arthroplasty

### **Study objectives**

Does the use of an iliac suction device improve the clinical or radiological result of acetabular component survival primary total hip replacement?

### **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: Primary hip arthroplasty

### **Interventions**

Patients undergoing primary total hip replacement will be randomised at the time of surgery. They will undergo the gold standard Exeter hip replacement in the usual fashion. Half of the patients will have the iliac suction device applied at the time of socket insertion. Half of the patients will not. All will be followed up in the out-patient clinic at 6-8 weeks, 6 months, and at 1, 2, 4 and 5 year intervals. All of our usual post surgery measures will be followed. In addition, each patient will undergo radiostereometric analysis (RSA) examination at each of the attendances. At the end of 5 years, all results will be analysed and reported.

### **Intervention Type**

Device

### **Phase**

Not Specified

### **Primary outcome(s)**

The aim of the study is to perform a randomised controlled trial assessing the effectiveness of the iliac suction device in improving the bone-cement interface in primary total hip replacement.

Outcome measures including complications, clinical scores, gross radiological appearances and also movement assessed by the technique of 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**

31/07/2007

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

1. Aged between 55 and 80 years old
2. Patients undergoing uncomplicated primary hip replacement

Therapeutic research. 12 Patients in each arm of trial.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Not Specified

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

30/08/2002

**Date of final enrolment**

31/07/2007

**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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/03/2009		Yes	No