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

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/10/2017	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
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

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: 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 measure
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.

Secondary outcome measures
Not provided at time of registration

Overall study start date
30/08/2002

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
24

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
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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2009		Yes	No