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Clinical evaluation comparing minimally invasive and standard skin incisions in cementless total hip arthroplasty using the Bimetric Hip system with the 38mm M2A cup. Clinical evaluation of incision size in total hip replacement

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 28/09/2007	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 18/05/2017	**Condition category** Surgery	[ ] Individual participant data [ ] Record updated in last year

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
N0360178753

Study information

Scientific Title
Clinical evaluation comparing minimally invasive and standard skin incisions in cementless total hip arthroplasty using the Bimetric Hip system with the 38mm M2A cup. Clinical evaluation of incision size in total hip replacement

Study objectives
1. Does a small incision (minimally invasive) provide an improved recovery for patients following total hip arthoplasty?
2. Specifically, is the patient able to mobilise more rapidly, leading to an early discharge from the hospital and does it require less analgesia for control of pain?
3. Are there any complications of performing this procedure that are not observed when using the standard incision?

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: Arthroplasty

Interventions

Patients will be randomised into either the control or test group (small incision) using randomisation envelopes. The envelope will be opened to reveal the study group only when the patient is in the anaesthetic room being prepared for surgery.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Clinical results following minimal incision hip surgery with regards to clinical scores at 6 weeks to 2 years post-operatively.

Secondary outcome measures
Not provided at time of registration

Overall study start date
19/07/2005

Completion date
31/01/2007

Eligibility

Key inclusion criteria
1. <75 years of age
2. Eligible for a cementless primary total hip replacement
3. Pre-op level of pain and function for conventional joint replacement
4. Likelihood of obtaining relief of pain and improved function
5. Full skeletal maturity
6. Ability to follow instructions
7. Good general health for age
8. Willing to return for follow-up evaluations

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
19/07/2005

Date of final enrolment
31/01/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North Hampshire Hospital NHS Trust
Basingstoke
United Kingdom
RG24 9NA

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name
North Hampshire Hospitals 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