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

Plain English summary of protocolNot provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 planNot 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