

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/05/2017	Condition category 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

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Additional identifiers

Protocol serial number
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 arthroplasty?
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

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)

Funder(s)

Funder type

Government

Funder Name

North Hampshire Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration