ISRCTN90825575 https://doi.org/10.1186/ISRCTN90825575

Does a small incision at the time of total hip replacement confer an advantage to patients by comparison to a standard incision?

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 18/10/2017	**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
N0203132067

Study information

Scientific Title
Does a small incision at the time of total hip replacement confer an advantage to patients by comparison to a standard incision?

Study objectives
Does a small incision at the time of total hip replacement (THR) surgery confer any advantage to patients by comparison to a 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: Total hip replacement

Interventions
Randomised controlled trial - 128 patients undergoing primary total hip replacement will be randomised at time of surgery. They will undergo the gold standard Exeter hip replacement in the usual fashion. Half of the patients will have a standard incision (length no less than 14 cm) and half will have an incision not to exceed 10 cm in length. Peri-operative blood loss will be measured as will a comparison between pre and post-operative haemoglobin levels. Post-operative limb swelling will be measured on the third post-operative day and at follow-up clinics at 6 weeks and 6 months post-op. Pain scores will be taken at 3 days post-op, and at 6 weeks and 6 months. Length of hospital stay will be measured from the day of surgery. Routine hip scores using the Charnley scoring system, and Oxford and Harris Hip scores will also be taken at the 6 month follow-up period. To avoid bias, the post-operative limb measurements will be performed by a non-surgeon clinical assistant, who will be blinded to the wound size as it will be covered by

an identical sized dressing in both arms of the study. The patient will be unaware of their wound size at the time of the third post-operative day pain scoring as again, the wound will be covered at this stage. At the end of the study all data will be analysed and reported.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
The aim of the study is to provide an evidence base regarding the most appropriate wound size in primary hip replacement. If significant benefit is found in one arm of the trial compared to the other, this practise will be adopted across the HIP Unit in primary THR. Thus, the research question that is being asked is: Does a small incision confer any greater benefit to patients when compared to use of a standard incision in primary total hip replacement? We plan to perform a randomised, controlled prospective trial to answer this question.

Study endpoints: Comparison of peri-operative blood loss, post-operative haemoglobin levels and need for transfusion, length of hospital stay, comparison of operated limb swelling, pain measurement.

Secondary outcome measures
Not provided at time of registration

Overall study start date
18/09/2003

Completion date
31/12/2005

Eligibility

Key inclusion criteria
Any patient undergoing routine primary total hip replacement will be eligible. They will be approached at pre-assessment clinic and offered the opportunity to be involved in the research. Informed written consent to partake will be mandatory for inclusion and any patient who declines will be excluded. If they are happy to consent at this stage, consent will be given. If they require an opportunity to discuss the study with their family or GP, they may do so, and at time of admission to hospital for surgery will sign the consent form if they are happy to be included. Adult subjects only - of any age.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
18/09/2003

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Devon & Exeter Hospital (Wonford)
Exeter
United Kingdom
EX2 5DW

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

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

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