ISRCTN18887807 https://doi.org/10.1186/ISRCTN18887807

A comparison of psoas compartment and subarachnoid blocks for 'fast track' total hip arthroplasty

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 01/09/2015	**Condition category** 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
N0544183632

Study information

Scientific Title
A comparison of psoas compartment and subarachnoid blocks for 'fast track' total hip arthroplasty

Study objectives
The aim of our study is to compare the reduction in morphine consumption, length of hospital stay and quality of rehabilitation in patients managed with intravenous patient controlled analgesia (PCA) with morphine combined with a subarachnoid block versus PCA morphine combined with a psoas compartment block for 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: Total hip arthroplasty

Interventions
The aims of our study are to compare, in patients undergoing total hip replacement (THR) operation, the reduction in morphine consumption, length of hospital stay, side effects and quality of rehabilitation in patients managed with intravenous patient controlled analgesia (PCA) with morphine combined with a subarachnoid block versus PCA morphine combined with a psoas compartment block for total hip replacement.

Informed consent will be taken from all patients recruited to the study. General anaesthesia will be administered to all patients in the anaesthetic room.

Two groups of 25 patients each will be required to detect a significant difference in outcome. Patients in both groups will receive morphine intraoperatively (the dose being decided on basis of their weight) and PCA morphine postoperatively.
Patients in Group A will have a psoas compartment block while patients in Group B will have a subarachnoid block. Patients in both the groups will receive PCA morphine for post operative analgesia. All patients will also receive paracetamol and ibuprofen postoperatively if there are no contraindications to use of these medicines. To ensure validity and reproducibility of the study, it is important to ensure that every patient recruited for the study should have an equal chance of being assigned to either of the two groups. This is called randomisation and will be performed by a drawing of a card with a computer-generated number that will assign the patient to either of the two groups. The card will carry a number, which can be cross-referenced to the technique performed. Only this number will appear on the data collection sheet and will be used to identify the patient. The anaesthetist performing the block will not be involved in further intra-operative management of the patient. The surgeons, physiotherapists and nursing staff collecting the data postoperatively will also be blinded to the patient's group.

In the postoperative period, data on morphine consumption as determined by use of the PCA pump will be collected. Pain scores will be recorded by a trained nurse. Hip and knee flexion, straight leg raise and mobility scores will be recorded by the attending physiotherapist. The number of days to discharge from the hospital will also be recorded. The collected data will be statistically analysed for differences between the two groups.

Traditional techniques for THR surgery are associated with significant post-operative pain, which, without adequate analgesia, lead to unnecessary morbidity, and a delay in recovery and subsequent discharge. Regional blockade has reduced the need for opioid analgesia and thereby reduces their potential side effects. Many studies have shown that a regional technique not only reduces opioid requirement but significantly improves a patient's outcome in terms of rehabilitation, analgesia, patient satisfaction and time to discharge. In addition, in hip surgery, regional blockade has been
shown to reduce blood loss and thrombo-embolic events. Psoas compartment and subarachnoid blocks for total hip replacement operation have been evaluated in a few studies but there is lack of consensus on their efficacy in providing pain relief and reducing morphine consumption.

Total hip replacement has been performed for more than forty years with admirable success and is currently a very cost-effective procedure, which contributes significantly to a patient's quality of life. We propose to evaluate effect of psoas compartment and subarachnoid blocks in patients undergoing THR.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Morphine

Primary outcome measure
Reduction in peri-operative morphine consumption

Secondary outcome measures

1. Early mobility
2. Early rehabilitation

Overall study start date
01/08/2006

Completion date
01/08/2007

Eligibility

Key inclusion criteria
1. All patients, between the ages of 18 and 85 years undergoing total hip replacement (THR) at the Addenbrooke's NHS Trust
2. ASA physical status I to III

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. ASA greater than III
2. Age below 18 and above 85 years old
3. Weight or BMI exclusion <50 or> 120 kg [BMI <20>35]
4. Inability to use a PCA (dementia, psychiatric problems, intellectual disability)
5. Contraindication to NSAIDs (asthmatics with significant sensitivity to aspirin, renal impairment, severe liver dysfunction, history of gastric ulceration or bleeding)
6. Opioid dependence or chronic pain syndromes
7. Contraindication to neuro-axial blockade or regional techniques - bleeding diathesis, anti-coagulation, absolute local anaesthetic (LA) allergy, localised infection, concurrent peripheral neuropathy or nerve injury

Date of first enrolment
01/08/2006

Date of final enrolment

01/08/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrooke's Hospital
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Sponsor information

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

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Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (UK), Own Account NHS R&D Support Funding

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