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

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

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Rakesh Tandon

**Contact details**
Consultant Anaesthetist
Department of Anaesthetics
Box 93
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 2QQ

## Additional identifiers

**Protocol serial number**
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

## Primary study design
Interventional

## Study design
Randomised controlled trial

## Study type(s)
Treatment

## 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(s)
Reduction in peri-operative morphine consumption

### Key secondary outcome(s)
1. Early mobility
2. Early rehabilitation

### 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

**Healthy volunteers allowed**
No

**Age group**
Adult

**Lower age limit**
18 Years

**Upper age limit**
85 Years

**Sex**
All

**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**
United Kingdom

England

**Study participating centre**
**Addenbrooke's Hospital**
Cambridge
United Kingdom
CB2 2QQ

# Sponsor information

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

# Funder(s)

### Funder type
Government

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

# Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration