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A comparison of two regional blocks for TKR, with or without sciatic nerve block: Psoas Compartment Block with neural catheter with and without sciatic nerve block and Femoral Sheath Block with neural catheter with or without sciatic nerve block

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Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 18/08/2015	**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
N0544174212

Study information

Scientific Title
A comparison of two regional blocks for TKR, with or without sciatic nerve block: Psoas Compartment Block with neural catheter with and without sciatic nerve block and Femoral Sheath Block with neural catheter with or without sciatic nerve block

Study objectives
Is the 'psoas compartment' lumbar plexus block in combination with or without a sciatic nerve block, or a 'femoral sheath' lumbar plexus block with a sciatic nerve block, used for total knee replacement surgery better than the 'femoral sheath' lumbar plexus block alone, in terms of reduced requirements for morphine analgesia?

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 knee replacement (TKR)

Interventions
The primary aim of this study is to determine if there is a difference, as measured by a decrease in morphine consumption, between two forms of lumbar plexus block in combination with or without a sciatic nerve block, in total knee replacement surgery. The study is also designed to

look at a difference in rehabilitation goals as set out by the physiotherapists and surgeons. It will also give more information on the nature of the blocks and their speed of onset.
It is a randomized study, with those collecting the postoperative data blinded to the nature of the block.
The patient, once recruited, will be randomized to one of 4 groups. Two of the groups will receive a 'psoas compartment' lumbar plexus block. One of these will have this block alone and the other with a sciatic nerve block. The other two groups will receive a 'femoral sheath' or 'perivacular' lumbar plexus block. One receiving an additional sciatic nerve block and the other not. All four groups will have a neural catheter put in place.
Each block will be performed prior to surgery in the anaesthetic room under a light sedation. Once the block has been performed it is tested by the anaesthetist to make sure it is working. Once this is established, the patient will have general anaesthetic as deemed appropriate by the attending anaesthetist.
Following the surgery a continuous infusion of local anaesthetic solution will be applied via the catheter placed when the block was performed. It will be in place for the first 24 hours postoperatively.
All patients will have 'rescue' analgesia including a morphine patient controlled analgesia pump. This will allow the study to look at morphine consumption. Side effects associated with the use of morphine will also be noted.
Over the following days the data on the morphine consumption as determined by the use of the morphine pump will be collected. Pain scores will be collected by the pain nurses. Knee flexion, straight leg raise and mobility scores recorded by the attending physiotherapist. The number of days to discharge from the hospital will also be recorded.
Once the all the data is collected it will be statistically analysed with the other three groups being compared to the 'femoral sheath' lumbar plexus block without sciatic nerve block, the groups will also be compared to each other, for significant differences in the parameters being studied.
Data collected during the assessment of the block will also be analysed.
There are conflicting studies within the scientific literature when comparing the efficacy of these blocks in total knee
replacement surgery. Some of the studies fail to show a difference in pain scores and morphine use, whereas some do.
The addition of the sciatic nerve block to these blocks also come up with conflicting answers. Many of these studies have been underpowered. Some have confounding factors in the protocol, such as, the use of concurrent regional techniques, such as, spinal anaesthesia. Some of the studies have not performed the blocks prior to the surgery or if they have have not 'started' the block by infusing local anaesthetic until the surgery is completed. Some theories on pain suggest that this may actually increase there sensitivity to pain if the pain signals are not blocked from the start, this is called 'wind-up'. Many of the studies assess the blocks incorrectly, either before or after surgery. It is therefore unclear if the blocks are working as well as they should or at all. This protocol is designed to address these short falls in the existing literature and therefore shed some new light on the best block or blocks to use.
The results of this study will aim to change clinical practice in this hospital and other institutions that perform a similar service.
Please note that we do not think it is ethically appropriate to include a PCA alone group. Though this may be the traditional control, the investigators experience and that in the literature (using this control), it is associated with unacceptable amounts of post-operative pain and morphine use.
Since this study includes methods, materials and techniques not outside usual or acceptable anaesthetic practice, no consultation with prospective research participants or the concerned communities from which they have been drawn, has been entered into.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
A reduction in postoperative morphine usage, as measured by morphine PCA, by 30% when compared to 'femoral sheath' block without sciatic nerve block.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2005

Completion date
01/09/2006

Eligibility

Key inclusion criteria
1. All patients over the age of 18 undergoing total knee replacement (TKR) at the Addenbrookes NHS Trust
2. American Society of Anesthesiologists (ASA) physical status I - III

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
104

Key exclusion criteria
1. ASA IV and V
2. Age: less than 18 years old. There is no upper limit
3. Inability to use a PCA (Dementia, psychiatric problems, intellectual disability). A morphine PCA is the best way to monitor the use of morphine in the study.
4. Contraindication to non-steroidal anti-inflammatory (NSAIDs) (asthmatics with significant sensitivity to aspirin, renal impairment, severe liver dysfunction, history of gastric ulceration or bleeding). NSAIDs are a useful adjunct to pain relief and are necessary to be prescribed in the study.

5. Opioid dependence or chronic pain syndromes. The morphine use in this group would be difficult to interpret and may skew the data.
6. Contraindication to neuro-axial blockade or regional techniques; bleeding diathesis, anti-coagulation, absolute LA allergy, localized infection or relative contraindications of concurrent peripheral neuropathy or nerve injury.
7. Use concurrently of any other regional technique (such as spinal anaesthesia, epidural). These would interfere with the primary aim, that is, we are comparing nerve blocks not in conjunction with spinal or epidural anesthesia.

Date of first enrolment
01/09/2005

Date of final enrolment
01/09/2006

Locations

Countries of recruitment
England

United Kingdom

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Sponsor information

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Record Provided by the NHSTCT Register - 2006 Update - Department of Health

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Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's Hospital (UK), 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