ISRCTN75639135 https://doi.org/10.1186/ISRCTN75639135

Hamstrings graft donor site infiltration with bupivacaine for pain relief after arthroscopically assisted anterior cruciate ligament reconstruction

Submission date
28/09/2007

Recruitment status
No longer recruiting

Registration date
28/09/2007

Overall study status
Completed

Last Edited
12/10/2017

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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

Protocol serial number
N0077186661

Study information

Scientific Title
Hamstrings graft donor site infiltration with bupivacaine for pain relief after arthroscopically assisted anterior cruciate ligament reconstruction

Study objectives
Does long acting local injected anaesthetic around the hamstrings in addition to femoral nerve block provide better post operative pain relief then femoral nerve block alone in patients having ACL reconstruction with the new ligament taken from their hamstrings tendon?

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: Anterior cruciate ligament reconstruction

Interventions
On postoperative ward rounds it has been noted that patients often complain that they have pain I their hamstrings during the first 24 hours after surgery. After consultation with the anaesthetic department it has been proposed that the femoral nerve block currently administered for pain relief does not alleviate this pain sufficiently and a more localised infiltration to this area may be variable form person to person. To perform a block on each individual nerve would be impractical as their anatomy is variable and blocks to the obturator nerve are challenging procedure. A local infiltration (injection) at the site of pain is quick, easy and safe and should negate the need for this.

Patients agreeing to take part will be randomly assigned to one of two groups, both of which will receive our current standard post-operative pain relief of femoral nerve block and oral pain killers. The first group (case) will also receive local anaesthetic into the hamstrings (0.375% bupivacaine) and the second group (control) will receive saline into the hamstrings.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
Post operative pain scores in the region of the hamstrings

Key secondary outcome(s)
Not provided at time of registration

Completion date
31/05/2007

Eligibility

Key inclusion criteria
Patients having primary anterior cruciate ligament reconstruction with hamstrings ipsilateral hamstrings tendon graft, under spinal anaesthesia

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Patients unwilling to participate
2. Those undergoing any procedure other than that described as inclusion criteria
3. Patients unable to consent for themselves
4. Patients with a known allergy to bupivacaine
5. Patients with peripheral neuropathy

Date of first enrolment
29/08/2006

Date of final enrolment
31/05/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Derby Hospitals NHS Foundation Trust
Derby
United Kingdom
DE1 2QY

Sponsor information

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

Funder(s)

Funder type
Government

Funder Name
Derby Hospitals NHS Foundation Trust (UK), NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration