

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

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<b>Registration date</b> 28/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/10/2017	<b>Condition category</b> Surgery	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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

## 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 to request a patient information sheet

## 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 measure**

Post operative pain scores in the region of the hamstrings

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

29/08/2006

**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

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

50

**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**

England

United Kingdom

**Study participating centre**

**Derby Hospitals NHS Foundation Trust**

Derby

United Kingdom

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## **Sponsor information**

**Organisation**

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

**Sponsor details**

The Department of Health

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**Sponsor type**

Government

**Website**

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

Derby Hospitals NHS Foundation Trust (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