

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	<input type="checkbox"/> Prospectively registered
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/10/2017	Condition category 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

Contact name
Mr G Geutjens

Contact details
Derby Hospitals NHS Foundation Trust
Trauma & Orthopaedics Department
Derbyshire Royal Infirmary
London Road
Derby
United Kingdom
DE1 2QY

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

DE1 2QY

Sponsor information

Organisation

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

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

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