

The morphine-sparing effect of continuous intra-articular infusion of bupivacaine following knee arthroplasty - a randomised double-blind placebo-controlled trial

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/07/2014	Condition category Signs and Symptoms	<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

Protocol serial number

N0009109897

Study information

Scientific Title

Study objectives

The continuous infusion of bupivacaine intraarticularly will decrease the postoperative morphine requirement following knee arthroplasty surgery.

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

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Signs and Symptoms: Pain

Interventions

60 patients scheduled to undergo primary knee replacement will be divided into two groups of 30 each. All of them will receive spinal anaesthesia for the surgical procedure and at the end of the procedure, a 18 G epidural catheter will be inserted into the joint aseptically. Both the groups will receive a continuous infusion of either 0.25% bupivacaine or normal saline respectively into the joint for 48 h in the postoperative period. All of them will receive morphine PCA postoperatively for analgesia along with non-steroidal anti-inflammatory agents as per protocol. The prospective pain relief, morphine and other analgesic requirements will be assessed. The side effects, if any, will be noted. The results will be analysed statistically.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Pain score, sedation score, PCA morphine consumption and co-analgesic consumption will be noted postoperatively at regular intervals.

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/07/2003

Eligibility

Key inclusion criteria

The study population will consist of patients admitted by the Department of Orthopaedics, QEH, for unilateral primary knee arthroplasty who are willing to take part in the study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/09/2001

Date of final enrolment

31/07/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Anaesthetic Department

Gateshead

United Kingdom

NE9 6SX

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

Gateshead Health NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration