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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	[ ] Prospectively registered [ ] Protocol
Registration date 12/09/2003	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 01/07/2014	**Condition category** Signs and Symptoms	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2001

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
60 patients

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

England

United Kingdom

Study participating centre
Anaesthetic Department
Gateshead
United Kingdom
NE9 6SX

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Gateshead Health NHS Trust (UK)

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