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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
12/09/2003	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2003	Completed	Results
Last Edited	Condition category	Individual participant data
01/07/2014	Signs and Symptoms	<ul><li>Record updated in last year</li></ul>

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Philip Mathew

#### Contact details

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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