ISRCTN33488737 https://doi.org/10.1186/ISRCTN33488737

# Effectiveness of Patient Controlled Epidural Analgesia (PCEA) compared with Continuous Epidural Infusion Analgesia (CEIA) in patients undergoing elective Large Bowel Resection

**Submission date**
23/01/2004

**Recruitment status**
No longer recruiting

**Registration date**
23/01/2004

**Overall study status**
Completed

**Last Edited**
04/03/2010

**Condition category**
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Jeremy Nightingale

**Contact details**
Anaesthetic Department
Portsmouth Hospitals NHS Trust
Queen Alaxandra Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY
+44 (0)1705 286279
captainsensible@soberton.swinternet.co.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

### ClinicalTrials.gov number

### Secondary identifying numbers
SEO130

# Study information

### Scientific Title

### Study objectives
The purpose of this investigation is to determine whether analgesia provided by Patient Controlled Epidural Analgesia (PCEA) is more effective than Continuous Epidural Infusion Analgesia (CEIA) in patients undergoing major abdominal surgery.
This knowledge would allow acute pain services to plan either to provide PCEA as a routine service, or to confine their services to continuous infusion epidural analgesia.

### 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

### Health condition(s) or problem(s) studied
Symptoms and general pathology: Pain

### Interventions
i. PCEA or ii. CEIA using Bupivacaine 0.125% with Fentanyl 4 µg/ml via a Graseby 9500 pump. Patients in both groups will receive a loading dose of bupivacaine 0.25% via the epidural catheter, which is then attached to the pump. For patients in the CEIA group (controls) the pump will be programmed to deliver a continuous infusion of 10 ml/hour but the patient demand

button will be disabled although it will still make a 'click noise' when pressed. For those in the PCEA arm, the pump will be programmed to deliver a continual dose of 8 ml/hour and a bolus dose of 3 ml on activation of the patient demand button, with a lockout interval of 20 min.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
a. Pain scores: This will be recorded using the hospital standard system which has been adopted by Wessex Acute Pain Forum as part of the minimum data set. It is a simple numerical scale of 0-3. In addition a standard 10 cm Vas marked at either extreme is used. Data will be collected hourly for the first 4 hours and 4 hourly thereafter. Patient will be scored at rest and on movement.
b. Patient's perception on control: In order to incorporate the notion of control we will utilise a standardised questionnaire to measure 'beliefs about controlling pain'
c. Patient's overall satisfaction of their pain control: at 72 hours and on discharge (between days 7-10), patients will be asked to record their overall impression of their pain control
d. Side effects: All patients will be assessed for incidence of sedation, nausea and vomiting, and respiratory depression. Pruritus and urinary retention will be noted and treated accordingly.
e. Analgesia usage: Consumption of epidural drugs and requirement for rescue analgesia will be recorded for all patients

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/10/2000

### Completion date
30/09/2003

## Eligibility

### Key inclusion criteria
Adult patients admitted to the Queen Alexandra Hospital for elective large bowel resection will be approached.

### Participant type(s)
Patient

### Age group
Not Specified

### Sex
Not Specified

### Target number of participants

Not provided at time of registration

### Key exclusion criteria
Patients with contra-indication to epidural analgesia, poor co-ordination and hand arthritis.

### Date of first enrolment
01/10/2000

### Date of final enrolment
30/09/2003

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Anaesthetic Department**
Portsmouth
United Kingdom
PO6 3LY

## Sponsor information

### Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

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

# Funder(s)

**Funder type**
Government

**Funder Name**
NHS Executive South East (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

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/03/2007 | | Yes | No |