

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	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/03/2010	Condition category Signs and Symptoms	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

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

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre
Anaesthetic Department
Portsmouth
United Kingdom
PO6 3LY

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

NHS Executive South East (UK)

Results and Publications

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