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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

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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
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PO6 3LY

Sponsor information

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

Sponsor details
The Department of Health
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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