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Are the sympathetic sensorimotor changes induced by thoracic epidural anaesthesia such that mobilization is possible?

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 29/09/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 29/04/2015	**Condition category** Surgery	[_] 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
N0054174157

Study information

Scientific Title
Are the sympathetic sensorimotor changes induced by thoracic epidural anaesthesia such that mobilization is possible?

Study objectives
To determine if the degree of haemodynamic and sensorimotor changes caused by a thoracic epidural infusion can allow early mobilization in patients having thoracotomies and if an opiate only epidural facilitates early mobilization. To determine if patients having thoracic epidural analgesia for thoracotomies can be mobilized early in the post operative period. The effect of the thoracic epidural on blood pressure, sensation, strength, co ordination, vibration sense and proprioception (the ability to sense the position of a limb in space). Scientific Basis: Patients having thoracotomies usually receive thoracic epidural analgesia. A local anaesthetic and opiate drug are usually used in combination to provide pain relief. The presence of a thoracic epidural especially the local anaesthetic component has been thought to produce weakness of the limbs and sensory changes that prevent patients from being mobilized. However mobilization of these patients has many benefits in terms of their respiratory function and overall recovery. There has been no previous work to show that early mobilization is possible in the presence of a functioning epidural in our group of patients. We hope to demonstrate that using an opiate only epidural will make early mobilization a possibility.

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Thoracotomy

Interventions

A total of 80 patients who have been listed for elective thoracotomy for whom epidural analgesia has been agreed will be invited to participate in the study on the day before their operation. The epidural will be sited before the operation and following surgery the functioning of the epidural will be confirmed. A combination of local anaesthetic and opiate (morphine like drug) will be administered via the epidural and the patient sent to the ward to receive their routine postoperative care.
They will be visited at 24, 48 and 72 hours during the postoperative period. At the 24 hour visit the epidural solution will be changed, so that the patient receives one of the previously coded syringes. The investigators will have been blinded as to the contents of the syringes. The patients will either receive a combination of local anaesthetic and opiate or an opiate alone. A series of measurements will be obtained during these visits, which are designed to elicit if the patient is able to mobilize safely. These will include measurement of blood pressure in the sitting and standing position, assessment of strength in the legs and arms. Different modalities of sensation will be tested including coordination and proprioception (the ability to sense the position of a limb in space). Pain will be assessed using the visual analogue scale. The subjects will then be asked if they experience any symptoms like headache, nausea, dizziness or blurring of vision. If they are found to fit the criteria then patients will be invited to mobilize with the help of assistants. Patients will only be asked to mobilize at the 48 hour and 72 hours visits.
Date: 08/08/2005 Reference: 05/Q1501/123 Online Form
NHS REC Application Form – Version 4.1 4 AB/38774/1

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Demographic data will be recorded: age, height, weight, hand dominance, ASA classification, preoperative medication, surgical procedure, blood loss and level of surgical incision. Primary outcome: The ability to walk with a thoracic epidural.

Secondary outcome measures
The effect of thoracic epidural blockade on each of the following measurements-systolic, diastolic, mean blood pressure, heart rate change when moving from the sitting to the upright position, leg motor power, dominant side hand grip strength, proprioception, vibration sense, and co ordination.

Overall study start date
01/09/2005

Completion date
30/09/2006

Eligibility

Key inclusion criteria
All adult patients having elective thoracotomy under general anaesthesia with epidural analgesia for post operative pain relief at the Cardiothoracic Centre, Liverpool.

The statistical calculations were done based on a similar study looking at epidural analgesia in labor in an ambulatory patient (Anesth Analg 1993;77:919-24). This paper suggests a failure to ambulate in 10% of the patients in the fentanyl group. A difference of 25% between this and the fentanyl/bupivacaine group would be significant clinically. With an alpha error of 5% and a power of 89% then n=80, which is 40 patients in each group.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Patients unable to mobilize preoperatively due to pre existing neurological, cardiorespiratory or locomotor disease
2. Those with known autonomic nervous system dysfunction, those on beta blockers, those with moderate severe angina (Canadian Cardiovascular Society Class 3 or 4), those with diabetes, those with known allergy to bupivacaine/ fentanyl
3. Routine contraindications to epidural catheter placement will apply

Date of first enrolment
01/09/2005

Date of final enrolment
30/09/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Cardiothoracic Centre
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

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Funder(s)

Funder type
Government

Funder Name
The Cardiothoracic Centre Liverpool NHS Trust (UK), NHS R&D Support Funding

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