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Comparison of analgesic efficacy of posterior Transversus Abdominis Plane (TAP) catheters with epidural analgesia in patients undergoing laparoscopic colorectal surgery

Submission date
08/11/2011

Recruitment status
No longer recruiting

Registration date
26/01/2012

Overall study status
Completed

Last Edited
23/02/2016

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Pain relief is an important aspect of patient care after major operation on the abdomen. Currently there are limited options for providing pain relief after surgery on the abdomen. Pain relief by epidural (injection into a person's back to stop pain being felt) is considered to be the most effective. However epidural can cause both minor side effects like fall in blood pressure, headache, vomiting and major (rare) side effects like meningitis, epidural infection causing paralysis of the legs and nerve damage. Transversus Abdominis Plane (TAP) block is a new technique of blocking the pain carrying nerve system of the abdomen and thus provides pain relief after surgery on the abdomen. However by inserting a catheter (plastic tube) into the TAP, it would be possible to block the nerves without causing discomfort to the patient and thereby provide pain relief over a prolonged period after surgery. The technique has an excellent safety profile to date. The aim of this study is to compare pain relief efficacy of the ultrasound guided TAP block catheters with thoracic epidural infusions in terms of reduction in postoperative pain scores during the first 48 hours after lower abdominal surgery.

Who can participate?
Adult males and females aged between 18-90 who are scheduled for keyhole surgery of the lower bowel can participate.

What does the study involve?
70 adult patients will be randomly allocated to two groups: to receive either epidural catheter or TAP Catheters. Epidural will be inserted as standard. The TAP catheter will be inserted at the end of surgery while the patient is asleep under general anaesthesia. The patients will be followed up at six points over 48 hours to assess their pain at rest and on coughing, after which the study period will end for the participant.

What are the possible benefits and risks of participating?
Epidural analgesia is the standard form of pain relief after keyhole surgery on the bowel. Side

effects include low blood pressure, numb sensation in the legs, failure and rarely infection and epidural abscess. TAP catheter analgesia is considered safe and the participants are warned about risk of infection and extremely rarely bowel injury.

Where is the study run from?
Leicester General Hospital (UK)

When is study starting and how long is it expected to run for?
The study started recruiting from April 2011 and is expected to be completed in 24 months. The study will be recruiting for 24 months.

Who is funding the study?
The study has obtained funding from the National Institute of Academic Anaesthesia (NIAA)s AAGBI grant.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Version 5 (26/01/2011)

Study information

Scientific Title
Comparison of analgesic efficacy of posterior Transversus Abdominis Plane (TAP) catheters with epidural analgesia in patients undergoing laparoscopic colorectal surgery: A randomized controlled blinded trial

Acronym
TAP

Study objectives

The benefits of adequate postoperative analgesia after abdominal surgery include a reduction in the postoperative stress response, reduction in postoperative morbidity and in certain types of surgery, improved surgical outcome. Single shot posterior Transversus Abdominis plane (TAP) block have been shown to provide analgesia after abdominal surgery.

Until now there have been no clinical trials reported on the efficacy continuous posterior TAP catheter infusions after lower abdominal surgery. Pilot data from our centre show that posterior TAP catheter infusions can be a viable alternative to the two standard techniques for postoperative analgesia after lower abdominal surgery, namely epidural and opioid based analgesia. Before the posterior TAP catheter infusions gain widespread acceptance, they have to be compared against epidural analgesia which is considered the gold standard technique for providing postoperative pain relief after lower gastrointestinal surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leicestershire, Northamptonshire and Rutland Research Ethics Committee, 16/02/2011, ref: 11 /H0402/1

Study design
Randomized controlled blinded trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Adult patients undergoing laparoscopic colorectal surgery

Interventions
Epidural Arm: A thoracic epidural catheter will be sited before induction of general anaesthesia. The patient will receive up to 20 mls of 0.25% bupivacaine during the surgery. At the end of the surgery, the patient will be connected to a infusion of 0.125% bupivacaine mixed with fentanyl 2 microgram /ml at a rate of 6-12 mls/hr. The infusion device will be patient controlled epidural analgesia (PCEA).

TAP Arm: The patients randomized to the TAP catheter arm will receup to upto 10 mg of intravenous morphine to provide analgesia during the surgery. At the end of the surgery while the patient is under general anaesthesia, TAP catheters will be sited on either side in the posterior TA plane under ultrasound guidance. The patient will also receive single shot subcostal TAP blocks. Then the patient will be connected to a infusion of 0.25% levo-bupivacaine using a elastomeric pump. The infusion will run at 8 to 10 mls/hour.

The total duration of treatment will be 48 hours. Pain scores at rest and on coughing and Nausea scores will be collected preoperatively and at 6 time points after surgery. Patient satisfaction with the analgesia will be recorded at 48 hrs after surgery. Any complications with either technique will be recorded.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
Visual analogue scale (VAS) pain score on coughing at 24 hours after surgery

Key secondary outcome(s))
1. Pain score at rest
2. Postoperative nausea & vomiting score
3. Length of hospital stay.
4. VAS at 30 minutes, 6 hours, 12 hours, 36 hours and 48 hours after surgery
5. Patient Satisfaction at 48 hours
6. Complications with the two techniques

Completion date
12/04/2013

Eligibility

Key inclusion criteria
1. All patients aged over 18 years who are scheduled for elective laparoscopic colorectal surgery
2. The surgical incision extending from thoracic T10 to lumbar L1 dermatome
3. American Society of Anesthesiologists (ASA) Class 1, 2, and 3

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Lack of consent including from those patients who lack mental capacity to give informed consent
2. Patients with history of drug allergy to bupivacaine
3. Patients with history of chronic pain conditions: defined as patients with history of pain for above 3 months and who consume regular analgesics for their pain
4. ASA Class 4 and 5
5. The surgical incision extending above thoracic T10 dermatome

Date of first enrolment
18/04/2011

Date of final enrolment
12/04/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leicester General Hospital
Leicester
United Kingdom
LE5 4PW

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Research organisation

Funder Name
National Institute of Academic Anaesthesia (NIAA) AAGBI Fund (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	01/04/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes