

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/01/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/02/2016	Condition category Surgery	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 receive up to 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 measure

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

Secondary outcome measures

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

Overall study start date

18/04/2011

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

70

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

England

United Kingdom

Study participating centre

Leicester General Hospital

Leicester

United Kingdom

LE5 4PW

Sponsor information

Organisation

University Hospitals of Leicester NHS Trust (UK)

Sponsor details

Research & Development Office
Gwendolen Road
Leicester
England
United Kingdom
LE5 4PW

Sponsor type

Hospital/treatment centre

Website

<http://www.leicestershospitals.nhs.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

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	01/04/2014		Yes	No