

Efficacy of local anaesthetic transversus abdominis plane (TAP) blocks in laparoscopic colorectal surgery

Submission date 27/10/2008	Recruitment status Stopped	☒ Prospectively registered ☐ Protocol
Registration date 04/11/2008	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 04/02/2011	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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Study information

Scientific Title
A double blind, randomised, placebo-controlled trial investigating the use of levobupivacaine transversus abdominis blocks for colorectal laparoscopic surgery

Acronym

Study objectives

There is no difference in post-operative morphine requirements between patients receiving a transversus abdominis plane block versus placebo in elective laparoscopic colorectal surgery.

Ethics approval required

Old ethics approval format

Ethics approval(s)

West Sussex Ethics Council, pending approval as of 28/10/2008

Primary study design

Interventional

Study design

Randomised, double blind (subject, surgeon, anaesthetist, investigator, outcomes assessor), placebo controlled, parallel assignment trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Surgery for colorectal diseases

Interventions

1. Intervention group: transversus abdominis plane block (TAPB)

The skin will be prepared with 0.5% chlorhexidine solution spray in 70% v/v BEB. A high frequency (5 - 10 MHz) ultrasound machine (Titan Sonosite, Sonosite Inc, serial number 036CGP) which conforms to EN60601-1 will be placed in the region of the triangle of Petit whose boundaries are the latissimus dorsi, external oblique muscles and the anterior superior iliac spine. This delineates all three layers of the anterior abdominal wall. Placing a 4 inch 21G needle (Stimuplex A insulated needle CE 0123, B Braun) perpendicular to the anterior abdominal wall the ultrasound will be used to guide the appropriate point of skin puncture. Once in the correct plane between transversus abdominis and internal oblique a 20 ml syringe (Becton-Dickinson - Plastipak syringe) with 0.25% - 0.5% Chirocaine® (levobupivacaine) infiltrated bilaterally to a total of 40 ml of 0.25% - 0.5% Chirocaine® will be attached to the plastic tubing extending from the needle and infused feeling for resistance and watching for inappropriate infusion. This will be repeated on the other side and the formal surgery commences.

2. Placebo group: standard care

A similar technique is used to the one described above using 20 ml of normal 0.9% saline. A standard general anaesthetic will be used (to discuss with anaesthetists), regular post-operative analgesia in terms of paracetamol orally 1 g four times daily (qds) and diclofenac 50 mg three times daily (tds) will be given. In addition a patient-controlled analgesia (PCA) will be used with 1 mg boluses, 5 minute lockouts and a maximum of 10 mg an hour.

All patients stayed in post-anaesthetic care unit (PACU) for 1 hour and then moved to the ward unless otherwise indicated.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Levobupivacaine (Chirocaine®), paracetamol, diclofenac

Primary outcome(s)

Post-operative morphine requirement measured in mg via a patient controlled system and analysed according to mg/kg, assessed according to usage at 1, 12, 24 and 48 hours after the patient wakes up from the anaesthetic.

Key secondary outcome(s)

1. Total hospital stay (MM), documented at discharge
2. Pain scores on a visual analogue scale (VAS) and categorical scoring system at rest and on movement (defined as going from a supine to sitting position) or coughing. VAS pain scores and categorical scoring system scores will be taken at 1, 12, 24 and 48 hours after the patient wakes, and upon waking up on PACU.
3. Time to first analgesia bolus, documented on the PCA pump

Completion date

01/08/2009

Reason abandoned (if study stopped)

Hypothesis significantly changed

Eligibility

Key inclusion criteria

1. Men and women, over the age of 18 years
2. Receiving any type of elective, laparoscopic colorectal surgery for benign or malignant disease
3. Operations conducted at Worthing Hospital, West Sussex, by any of the colorectal surgeons

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Patients under the age of 18 years
2. Undergoing open or emergency surgery
3. A history of renal failure, coagulopathies or allergy to levobupivacaine
4. Reoperations for complications
5. Previous abdominal surgery
6. Not undergoing colorectal surgery
7. Patients in which an intentional stoma is to be fashioned
8. Refusal to participate

Date of first enrolment

01/02/2009

Date of final enrolment

01/08/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre**Worthing Hospital**

Worthing

United Kingdom

BN11 2HE

Sponsor information

Organisation

Worthing and Southlands Hospitals NHS Trust (UK)

Funder(s)

Funder type

Government

Funder Name

Worthing and Southlands Hospitals NHS Trust (UK) - Worthing Research Unit

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration