ISRCTN22165762 https://doi.org/10.1186/ISRCTN22165762

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

Submission date 27/10/2008	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 04/11/2008	**Overall study status** Stopped	
Last Edited 04/02/2011	**Condition category** Surgery	

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
N/A

Study information

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

Acronym
WORTHINGTAPTRIALUK

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

Study design
Randomised, double blind (subject, surgeon, anaesthetist, investigator, outcomes assessor), placebo controlled, parallel assignment 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
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® (levobupivicaine) 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)
Levobupivicaine (Chirocaine®), paracetamol, diclofenac

Primary outcome measure
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.

Secondary outcome measures
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

Overall study start date
01/02/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

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 levobupivicaine
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
England

United Kingdom

Study participating centre
Worthing Hospital
Worthing
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Sponsor information

Organisation
Worthing and Southlands Hospitals NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.worthinghospital.nhs.uk/

Funder(s)

Funder type
Government

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

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