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Clinical trial comparing epidurals to rectus sheath catheters for pain relief following major abdominal surgery

Submission date 16/01/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 16/01/2014	**Overall study status** Completed	
Last Edited 28/09/2018	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
After major abdominal surgery good pain relief is very important to recover quickly and avoid complications. At the moment the most common way of doing this in the UK is with an epidural. This is a fine tube placed in the spine through which local anaesthetic is given, numbing the nerve supply to the abdomen and controlling the pain. Epidurals can be very effective but they do have a number of possible side effects including headaches and low blood pressure (common), and nerve injury (very rare). Rectus Sheath Catheters (RSC) are another method of pain control which can be used when surgery involves a vertical incision. In this technique, local anaesthetic is infused directly into the abdominal wall, blocking the nerves around the wound site. An old technique, RSCs are now in use again as ultrasound allows doctors to site the catheters accurately between the muscle layers of the abdomen. Many of the side effects associated with epidurals do not apply to RSCs and this may be an advantage. However, no formal research has yet been conducted and so it is not known for sure which technique results in the best pain relief with the least side effects. This is the question that this study aims to answer.

Who can participate?
All patients over 18 years of age requiring planned open major abdominal surgery via a vertical incision are eligible.

What does the study involve?
Every patient who agrees to take part will be randomly allocated to one of two groups. After surgery, one group will receive an epidural and the other group will receive RSCs. All other aspects of patient care will remain unchanged. Information on pain relief, bowel function, side effects, complications, recovery and length of hospital stay (amongst other things) will then be collected by researchers and used for comparison. Some patients will also be interviewed one month after discharge, looking in more detail at their overall experience of hospital.

What are the possible benefits and risks of participating?
All patients participating will benefit from greater education and support of their pain

management and recovery after surgery. Information from this study may help to improve the care of surgical patients in the future. Each method has its own risks. Epidural commonly lowers blood pressure and may cause a headache. Nerve damage is possible but extremely rare. With both techniques there is a possible but rare risk that, too much local anaesthetic may be given. This can cause problems with the brain or heart. There is also a theoretical risk that organs inside the tummy might be damaged when the RSCs are put into place. So far, this has never happened to a patient. Patients in both groups of the study will be given a fentanyl patch. Fentanyl is a strong painkiller but it does also have some side effects. The most common ones are feeling sick, constipation and sleepiness. Whether an epidural or a RSC is used, there is a chance that it might not work well enough, resulting in pain after surgery. As both techniques are in use in clinical practice these risks are all possible whether participating in this study or not. Both epidurals and RSCs have been shown to work better than the alternative (morphine alone). If good pain control cannot be achieved via the epidural or RSCs patients will be given morphine as an alternative.

Where is the study run from?
Royal Blackburn Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2014 to June 2017

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
15847

Study information

Scientific Title
A randomised controlled trial of thoracic epidural analgesia versus rectus sheath catheters for open midline incisions in major abdominal surgery within an Enhanced Recovery Program

Acronym
TERSC

Study objectives
The aim of the TERSC study is to test the efficacy, safety and acceptability to patients of Rectus Sheath Catheters. The research question which TERSC seeks to answer is which is the best overall pain relief package between Rectus Sheath Catheters (RSCs) and Thoracic Epidural Analgesia (TEA) after planned open major abdominal surgery? The null hypotheses for the study are as follows:

1. Primary Null Hypothesis: there is no difference between pain scores on movement at 24 hours between patients randomly allocated to receive either RSC or TEA following planned open major abdominal surgery
2. Secondary Null Hypotheses include: there is no difference in pain scores (rest and movement) at 2, 6, 12, 24, 48 and 72 hours postoperatively, safety profile, functional recovery, cost-effectiveness and quality of recovery between patients randomly allocated to receive either RSC or TEA following planned open major abdominal surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Greater Manchester East, 21/11/2013, ref: 13/NW/0782

Study design
Randomised; Interventional; Design type: Not specified

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network, Generic Health Relevance and Cross Cutting Themes; Subtopic: Colorectal Cancer, Upper Gastro-Intestinal Cancer, Generic Health Relevance (all Subtopics); Disease: Colon, Duodenum, Pancreas, Stomach, Surgery, Anaesthetics

Interventions
Potentially eligible patients will be identified by their treating surgical team. If willing to discuss the trial further, their details will be passed on to researchers and written and verbal explanations of the study will then be given. The research nurse will meet with patients again at their pre-operative assessment clinic, and if they wish to participate will consent them and collect baseline demographic data before randomising them into the trial.

Patients will be stratified by operation type and age, with three surgical strata (radical cystectomies, major colonic excisions and major rectal excisions) and two age strata (up to and above 40 years of age). Of the 66 patients recruited into each arm of the study, we expect 50% to be major colonic excisions, 30% to be major rectal excisions and 20% to be radical cystectomy cases. Because we expect to see substantially more patients in the over-40 group, a 2:1 randomisation between the age groups is planned. It should be noted that the radical cystectomy group will only contain patients over the age of 40, and therefore in total there will only be five strata.
The randomisation process is electronic via the web-based InForm system maintained by Imperial CTU.

Patients and healthcare staff will both know which arm of the trial has been assigned and on the day of their operation patients will have either rectus sheath catheters or a thoracic epidural sited prior to surgery.

Research Arm A (Rectus Sheath Catheters)
Immediately following induction of anaesthesia, the anaesthetist, using ultrasound guidance, will insert bilateral RSC. An aseptic technique will be used. 20 ml of 0.25% bupivacaine will be injected into the potential space between the rectus muscle and the rectus sheath before catheters are sited. Once correctly placed, catheters will be tunnelled subcutaneously to a level above the xiphisternum.
45 minutes before the end of surgery a bolus of intravenous morphine will be administered for visceral pain. Once in the theatre recovery area, a fentanyl patch will also be applied and the two RSC catheters will be connected to the ambITR Mini infusion pump or ambiT PreSet pump. Pumps will deliver a bolus of 40 ml 0.2% ropivacaine over 24 minutes every 4 hours. This is via staff or the patient pressing the PCA button. There will be a 4-hour lock out set for safety.

Research Arm B (Thoracic Epidural Anaesthesia)
Prior to induction of general anaesthesia, an epidural will be sited by the anaesthetist at T7-T9 for a right sided colonic resection/upper GI surgery, or T9-T11 for a left sided resection or radical cystectomy. An aseptic technique will be used. 10 ml 0.25% bupivicaine with 100 mcg fentanyl will be given an as bolus to establish and test a block prior to surgery.
Following insertion, an epidural infusion of 0.125% bupivicaine and 2 mcg/ml fentanyl will be commenced at 10 ml/hr, then titrated to effect. On the second post-operative night a fentanyl patch will be applied after which the epidural will be weaned off.

In either arm, if breakthrough pain is experienced, the block will first be optimised with an additional bolus of the maintenance solution. Oxycodone as required will be used for further breakthrough pain within the first 48 hrs.
Complete absence of any sensory blockade following optimisation will be managed by a standard rescue protocol involving intravenous morphine; further details are given in Appendix 3.
Patients in both arms of the trial will receive all other hospital care according to our institutions Enhanced Recovery Program.
Data will be collected directly by researchers before, during and after surgery until hospital discharge. Patients will also contribute information via individual patient diaries. All data will be entered directly onto a trial-specific, web-based Case Report Form.

All patients will be followed up by telephone 4 weeks after surgery. Additionally, 20 patients (10 from each arm) will participate in a nested qualitative study 1 month after surgery. This will utilise semi-structured interviews conducted by an experienced qualitative researcher. Interviews will be face-to-face, and will take place at a location convenient to the participant

(usually their home). The interview schedule will consist of a flexible topic guide focusing on the participants expectations, experiences and outcomes. Thematic analysis will be applied to audio recordings and transcripts, whereby data will be categorised, coded, refined and further analysed for emergent themes.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
1. VAS pain scores at rest and movement (from supine to sitting position) at 2, 6, 12, 24, 48 and 72 hours after wound closure
2. Patient experience

Key secondary outcome(s))
1. Functional pain scores and opiate consumption
2. Recovery profile i.e. time to return of GIT function, time until surgically fit for hospital discharge and actual LOS
3. Morbidity including fluid balance, incidence of hypotension and Day 5 POMS score
4. Cost effectiveness and postoperative recovery scores

Completion date
01/06/2017

Eligibility

Key inclusion criteria
1. Patients over 18 years of age
2. Planned elective major abdominal surgery including major colorectal resections, upper GI surgery (e.g. pancreaticoduodectomy) and major urological surgery (e.g. radical cystectomy)
3. Planned open midline surgical incision
4. Included in the ERP
5. Willing and able to give consent
6. American Society of Anesthesiologists (ASA) score 13

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

All

Key exclusion criteria
1. Contraindication to epidural analgesia (e.g. coagulopathy, local infection, systemic sepsis, severe aortic stenosis)
2. Consent refused for either thoracic epidural analgesia (TEA) or Rectus Sheath Catheters (RSCs)
3. Non-English speaker
4. Ano-rectal excision (e.g. pan-proctocolectomy or AP resection)
5. Planned transverse or oblique incisional approach
6. Allergy to local anaesthetic drugs or opiates
7. Opiate tolerance
8. Pre-existing chronic abdominal pain
9. Extensive existing midline abdominal scarring

Date of first enrolment
02/02/2014

Date of final enrolment
05/01/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Sponsor information

Organisation
East Lancashire Hospitals NHS Trust (UK)

ROR
https://ror.org/002pa9318

Funder(s)

Funder type

Government

Funder Name
NIHR Research for Patient Benefit (RfPB); Grant Codes: PB-PG-0212-27122

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?
Protocol article	protocol	21/10/2014		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes