

# Rectus sheath pain control after major abdomino-pelvic surgery

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| <b>Submission date</b><br>16/02/2012   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>26/03/2012 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>14/06/2017       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Most patients undergoing abdominal surgery have an epidural catheter inserted – this is a small plastic tube placed into the back at the start of the operation which allows the anaesthetist to give local anaesthetic to numb the nerves coming from the spinal cord. A different method that has been used more recently involves placing small tubes just under the muscles in the front of the abdomen, called a ‘rectus sheath catheter’. This also allows local anaesthetic to be given down the catheters after the operation, thereby keeping the patient comfortable. The aim of our study is to test whether one of these techniques is better than the other, not just in terms of pain relief but also the safety of the procedures, the ability for patients to move around after the operation, as well as the amount of care that needs to be provided by the doctors or nurses during the patient's recovery.

### Who can participate?

Male or female patients aged 18 or over undergoing major abdomino-pelvic surgery.

### What does the study involve?

Participants will be randomly allocated into one of two groups. One group will have an epidural catheter placed for pain relief and the other group will have rectus sheath catheters. We will then study the differences between the two anaesthetic techniques. We will collect information from clinical notes and routine measurements on the ward such as blood pressure, pulse and temperature. We will also assess how mobile the participant is following the operation and how much time is required from the doctors and nurses to look after the anaesthetic catheters.

### What are the possible benefits and risks of participating?

We are studying this because there are potential benefits as well as disadvantages with both procedures and we would therefore like to look in a scientific manner to see whether one technique has a significant advantage over the other. We will use the results from this study to design a much larger study that will run in several hospitals in the UK. Our results will be published in the international medical literature so that other clinicians can see the findings. If the findings show an improved level of care for one technique compared to the other, we will encourage the use of the technique in other hospitals. For participants, there are no additional risks over and above the normal clinical care. Both anaesthetic techniques are currently in use in

the Royal Devon and Exeter NHS Foundation Trust. The procedures themselves obviously have potential risks which would be explained routinely to both study patients and patients having routine clinical care ahead of any surgery.

Where is the study run from?

Exeter Surgical Health Services Research Unit (UK).

When is the study starting and how long is it expected to run for?

From February to June 2012.

Who is funding the study?

The Research and Development Unit at the Royal Devon & Exeter NHS Foundation Trust (UK).

Who is the main contact?

Mr John McGrath (01392 406277)

Mr Thomas Dutton (01392 408940, thomas.dutton@rdeft.nhs.uk)

## Contact information

### Type(s)

Scientific

### Contact name

Mr John McGrath

### Contact details

Exeter Surgical Health Services Research Unit  
Royal Devon and Exeter NHS Foundation Trust  
Exeter  
United Kingdom  
EX2 5DW

## Additional identifiers

### Protocol serial number

N/A

## Study information

### Scientific Title

Rectus Sheath Catheters in Major Abdomino-Pelvic Surgery: a pilot randomised controlled trial

### Acronym

RSC-iMAPS

### Study objectives

Analgesia delivered by rectus sheath catheters is equivalent with respect to efficacy and safety when compared to epidural-based analgesia for patients undergoing major abdomino-pelvic surgery.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

NRES Committee South West, Cornwall and Plymouth, 07/11/2011, ref: 11/SW/0274

## **Study design**

Single-centre pilot randomised control trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Pelvic cancer

## **Interventions**

Epidural catheter versus rectus sheath catheter-based analgesia

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

Is rectus sheath catheter based analgesia equivalent to epidural based analgesia in patients undergoing major abdomino-pelvic surgery in terms of safety and efficacy?

Safety is assessed by recording the number of adverse events and complications associated with the trial. Efficacy is assessed by a number of means: patient pain scores, time to mobilisation, time to flatus, time to bowel opening, and readmission rate. The measurements are taken for the duration of the in-patient stay, and then up to 31 days post-operatively to record the readmission rate during this period.

## **Key secondary outcome(s))**

1. Procedural time
2. Total blood loss/transfusion
3. Hypotensive episodes
4. Urine output
5. Total intravenous fluids administered
6. Patient mobilisation
7. Opiate avoidance
8. Gastro-intestinal morbidity
9. Respiratory morbidity
10. Demands on nursing/medical care
11. Cost-effectiveness
12. Patient length of stay
13. Patient acceptability

The measurements are taken for the duration of the in-patient stay, and then up to 31 days post-operatively to record the readmission rate during this period

## **Completion date**

30/06/2012

## Eligibility

### Key inclusion criteria

1. Diagnosed with a surgical/medical condition requiring a midline laparotomy and exenterative procedure
2. Willing and able to provide informed consent for participation in the study
3. Male or female aged 18 years or over

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Sex

All

### Key exclusion criteria

1. Refusal to participate in the trial/provide informed consent
2. Unable to provide informed consent
3. Inappropriate surgical approach, e.g. laparoscopic
4. Contra-indications to an epidural catheter or rectus sheath catheter

### Date of first enrolment

15/02/2012

### Date of final enrolment

30/06/2012

## Locations

### Countries of recruitment

United Kingdom

England

### Study participating centre

**Exeter Surgical Health Services Research Unit**  
Exeter  
United Kingdom  
EX2 5DW

## **Sponsor information**

### **Organisation**

Royal Devon and Exeter NHS Foundation Trust (UK)

### **ROR**

<https://ror.org/03085z545>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

Royal Devon and Exeter Healthcare Trust (UK) - Small Grants Award 2010 ref: 20101207JM

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration