ISRCTN77620476 https://doi.org/10.1186/ISRCTN77620476

Rectus sheath pain control after major abdomino-pelvic surgery

Submission date
16/02/2012

Recruitment status
No longer recruiting

Registration date
26/03/2012

Overall study status
Completed

Last Edited
14/06/2017

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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
Pelvic cancer

Interventions
Epidural catheter versus rectus sheath catheter-based analgesia

Intervention Type
Procedure/Surgery

Primary outcome measure
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.

Secondary outcome measures

1. Procedural time
2. Total blood loss/transfusion
3. Hypotensive episodes
4. Urine output
5. Total intravenous fluids administered
6. Patient mobilisation
7. Opiate avoidane
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

Overall study start date
15/02/2012

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
88

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
England

United Kingdom

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)

Sponsor details
Royal Devon and Exeter Hospital
Barrack Road
Exeter
England
United Kingdom
EX2 5DW

Sponsor type
Hospital/treatment centre

Website
http://www.rdehospital.nhs.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

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