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A study investigating a continuous local anaesthetic infusion for pain relief after pelvic tumour surgery

Submission date 12/02/2015	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/02/2015	**Overall study status** Stopped	
Last Edited 19/05/2016	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A randomised, triple-blind, placebo controlled trial evaluating the analgesic efficacy of continuous paravertebral block (PVB) following hemipelvectomy for pelvic tumours.

Study objectives
Does a PVB block following hemipelvectomy provide better analgesia than the current treatment protocol?

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Birmingham Research Ethics Committee - submitted as of 20/02/2015

Study design
A prospective, randomised, triple-blind, placebo-controlled trial comparing the effects of continuous LA infusion with a placebo infusion of 0.9% sodium chloride following hemipelvectomy. This is a single centre study at the Royal Orthopedic Hospital, Birmingham.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients undergoing hemi-pelvectomy for pelvic tumours

Interventions
Patients will be randomised to receive one of two possible post-operative catheter infusions for 5 days:
1. Bupivicaine 0.125% infusion at a fixed rate of 10ml/hr.
2. 0.9% Sodium Chloride infusion at a fixed rate of 10ml/hr.
This will be in addition to standard post-operative analgesia which encompasses combined epidural and spinal anaesthetic, and patient controlled analgesia.

Intervention Type
Drug

Phase

Not Applicable

Primary outcome(s)

1. Pain score – measured by Numeric Rating Scales (NRS) (0-10)
1.1. Worst pain score
1.2. Least pain score
1.3. Frequency of severe pain (NRS 0-100%)
Pain will be measured at 4, 8, 12, 24 hours post-operatively using a validated questionnaire. It will be measured daily between 24 hours - 7 days and then weekly until discharge. A final questionnaire will be administered on the day of discharge.

Key secondary outcome(s))

1. Interference with activities (measured by NRS 0-10)
1.1. Activities in bed (e.g. turning, sitting up, changing position)
1.2. Breathing deeply/coughing
1.3. Sleep quality
1.4. If out of bed: activities out of bed (e.g. sitting in chair, walking with aids)
2. Side effects of opioid analgesia (measured by NRS 0-10)
2.1. Nausea
2.2. Drowsiness
2.3. Itching
2.4. Dizziness
3. Emotions (measured by NRS 0-10)
3.1. Anxiousness
3.2. Helplessness
4. Satisfaction with analgesia
4.1. Would you have liked more pain relief (Y/N)
4.2. Apart from this study did you receive any information about pain treatment options? (Y/N)
4.3. How satisfied are you with your pain treatment? (measured by NRS 0-10)
4.4. Have you used non-medicinal forms of pain relief?
5. Urinary retention
5.1. Time to urinary catheter removal (days)
5.2. Re-catheterisation within 24 hours of catheter removal (Y/N)
6. Post-operative ileus
6.1. Bowels open? Y/N
6.2. Passed flatus? Y/N
7. Quantity of opioid use for first five days post-operation (mg)
8. Duration of epidural infusion (hours)
9. Duration of intravenous analgesia (hours)
10. Wound infection rates (defined by antibiotics started for wound infection)
11. Time to first ambulation out of bed (days)
12. Length of High Dependency Unit (HDU) Stay (hours)
13. Length of hospital stay (days)
The subjective outcome measures will be assessed in the form of a previously validated questionnaire (please see Appendix). This questionnaire will be used in its entirety at 4 hours post-operation and again on the date of discharge. A minimally modified version will be utilised to investigate temporal changes in pain control between these time points. A Research Assistant (RA) will give the correct questionnaires to the patient who will complete them independently. Only in exceptional cases (e.g. patient unable to read, reading glasses not available, patient too weak to fill it in independently) will the researcher read the questions to the patient. The objective measures will be obtained by review of the patients' medical notes.

Completion date
01/08/2018

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Patients aged 18 and over
2. Known diagnosis of a pelvic malignancy (primary or secondary)
3. Undergoing a hemipelvectomy
4. Ability to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Exclusion criteria:
1. Do not consent to participation in the trial
2. Pre-existing pain syndromes that may affect perception of pain
3. History of opioid dependence
4. Previous adverse reaction to local anaesthetic
5. Established hepatic or renal insufficiency (CKD Stage 3 or greater)
6. A pre-existing clinical diagnosis of dementia
7. Pregnancy

Withdrawal criteria:
1. Failure to initiate therapy in line with the protocol
2. Unsuccessful insertion of paravertebral block catheter
3. Clinical evidence of wound or catheter infection
4. Adverse reaction to local anaesthetic
5. Respiratory support from invasive ventilation post-operatively

Date of first enrolment
01/04/2015

Date of final enrolment

01/04/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Royal Orthopaedic Hospital NHS Foundation Trust
Bristol Road South
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Sponsor information

Organisation
Royal Orthopaedic Hospital NHS Foundation Trust

ROR
https://ror.org/03dx46b94

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Orthopaedic Hospital NHS Foundation Trust

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request