

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

Submission date 12/02/2015	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/02/2015	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/05/2016	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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. Bupivacaine 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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/08/2014

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

80

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

England

United Kingdom

Study participating centre

The Royal Orthopaedic Hospital NHS Foundation Trust
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Sponsor information

Organisation

Royal Orthopaedic Hospital NHS Foundation Trust

Sponsor details

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/03dx46b94>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Royal Orthopaedic Hospital NHS Foundation Trust

Results and Publications**Publication and dissemination plan****Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Available on request