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Epidural versus Wound Infusion Catheter Study

Submission date 07/09/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/10/2009	**Overall study status** Completed	
Last Edited 27/11/2015	**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

Clinical Trials Information System (CTIS)
2009-014375-50

Protocol serial number
1.7

Study information

Scientific Title
Comparison of the efficacy of thoracic Epidural analgesia and a local anaesthetic Wound Infusion Catheter after laparoscopic colectomy within the Enhanced Recovery Programme: a pilot randomised controlled trial (RCT)

Acronym
E-WIC

Study objectives
Wound infusion catheter is at least as effective as epidural following laparoscopic colectomy within the Enhanced Recovery Programme.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West Research Ethics Committee, 01/02/2010, ref: 09/H0206/66

Study design
Pilot randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Laparoscopic colectomy within an enhanced recovery programme

Interventions
Patients recruited from colorectal outpatient clinic will be randomised to receive either epidural or wound infusion catheter.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Patient reported pain assessment. This will be assessed at baseline before the operation, on return to the ward after surgery and twice daily at 10.00 and 16.00 on days one and two post operatively. It will then be measured once daily until discharge and in outpatient follow up two weeks post operation.

Key secondary outcome(s))
1. Rescue analgesia. Analgesia log will be filled in daily by research nurse
2. Patient reported outcomes will be recorded pre operatively as baseline and prior to discharge by the research nurse using a structured questionnaire
3. Quality of life assessment using SF-36® Health Survey and Euroqol EQ-5D at baseline, prior to discharge and at two week follow up
4. A subset of 10 patients will be invited to take part in video recorded interviews at two week follow up to assess the success of blinding and to investigate the patient experience of taking part

5. Complications will be entered into a data sheet at discharge by the research fellow and followed up to 30 days to capture readmission, morbidity and mortality
6. Length of hospital stay will be recorded by the research nurse at discharge
7. Standard performance indicators using short physical performance battery will be assessed by the research nurse at baseline and 48 hours post operatively
8. Stress response to surgery and the effect of analgesic method will be investigated with blood samples taken at baseline, 3, 6, 12 and 24 hours after surgery. This will be performed by the research fellow or on call doctor to a strict protocol. The samples will measure epinephrine, cortisol, insulin and interleukin-6.

Completion date
07/02/2011

Eligibility

Key inclusion criteria
1. Both males and females, aged 18 or over
2. Patients undergoing elective laparoscopic colectomy for right or left sided benign or malignant tumour of the colon, with intention to cure
3. American Society of Anesthesiology score of I, II or III
4. Able to provide written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Transverse colon or rectal tumour
2. Locally advanced (T4) or widespread distant disease. Palpable mass.
3. Emergency admission or obstruction/perforated disease
4. Inflammatory bowel disease (Crohn's Disease or Ulcerative Colitis)
5. Known allergy to local anaesthetic
6. Multiple sclerosis or chronic pain requiring regular strong opiate drugs
7. Recent history of drug or alcohol abuse
8. Contraindication to epidural
9. Poor cognitive ability making consent or completion of questionnaires impossible
10. Pregnant women

Date of first enrolment

01/04/2010

Date of final enrolment
01/04/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Yeovil District Hospital
Yeovil
United Kingdom
BA21 4AT

Sponsor information

Organisation
Yeovil District Hospital NHS Foundation Trust (UK)

ROR
https://ror.org/00v5nyn36

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

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?
Results article	results	01/02/2013		Yes	No
HRA research summary			28/06/2023	No	No