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# Epidural versus Wound Infusion Catheter Study

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

**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**
2009-014375-50

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

## 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
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 measure

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.

### Secondary outcome measures
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.

### Overall study start date
29/11/2009

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
50

### 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
England

United Kingdom

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

## Sponsor information

### Organisation
Yeovil District Hospital NHS Foundation Trust (UK)

### Sponsor details
Yeovil District Hospital
Higher Kingston
Yeovil

England
United Kingdom
BA21 4AT

**Sponsor type**
Hospital/treatment centre

**Website**
http://www.yeovilhospital.nhs.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

**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

## 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 |