

# Conventional versus laparoscopic surgery for colorectal cancer within an Enhanced Recovery program

<b>Submission date</b> 23/07/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 30/08/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/10/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://www.cancerhelp.org.uk/trials/a-trial-looking-at-conventional-versus-keyhole-surgery-plus-ways-to-improve-recovery-for-people-with-bowel-cancer>

## Study website

<http://www.octo-oxford.org.uk/alltrials.html>

## Contact information

### Type(s)

Scientific

### Contact name

Dr Anne Francis

### Contact details

EnROL Trial Office  
Oncology Clinical Trials Office (OCTO)  
Department of Clinical Pharmacology  
Old Road Campus Research Building  
University of Oxford  
Old Road Campus, off Roosevelt Drive  
Headington  
Oxford  
United Kingdom  
OX3 7DQ  
+44 (0)1865 617017  
[enrol@octo-oxford.org.uk](mailto:enrol@octo-oxford.org.uk)

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## **Study information**

### **Scientific Title**

Conventional versus laparoscopic surgery for colorectal cancer within an Enhanced Recovery program

### **Acronym**

EnROL

### **Study objectives**

This study examines the hypothesis that laparoscopic surgery within an enhanced recovery programme will provide superior postoperative outcomes when compared to conventional open resection of colorectal cancer within the same programme.

Please note that as of 16/09/2008 this record was updated to include study design information on outcome observers, addition of ethics information, and a change to the primary and secondary outcomes. Please find details of all of these updates in the relevant field. Please also note that the contact for this trial has changed - the previous contact was Mr Robin Kennedy.

As of 04/01/2011 anticipated end date updated to 30/06/2012. Previous end date was 31/10/2009.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Added 16/09/2008: Oxford Research Ethics Committee B on 29/01/2008 (ref: 07/H0605/150)

### **Study design**

Phase III multicentre randomised controlled trial, with blinding of patients and outcome observers during the first week post-operatively

### **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**

Colorectal cancer

## **Interventions**

Randomisation procedures:

After completing suitability checks and consent forms for a patient, the site staff will call or fax a dedicated telephone to confirm the eligibility of the patient. The patient will then be randomised to receive one of the interventions below:

1. Open surgery
2. Laparoscopic surgery

After this, both groups will participate in the Enhanced Recovery Programme (see protocol below).

Preoperative investigations:

Prior to surgery, all patients should undergo complete colonic imaging by colonoscopy, barium enema or Computed Tomography (CT) scanning. Preoperative imaging should also include the chest and liver - preferably using CT. For rectal cancer, Magnetic Resonance Imaging (MRI) of the rectum should be undertaken to exclude a 'threatened margin'.

Preoperative radiotherapy and chemotherapy:

Pre-operative radiotherapy may be used in rectal cancer but should be standardised irrespective of the randomisation and treatment details recorded for each patient. Long course preoperative chemoradiotherapy is not a trial exclusion criterion except when used to treat a 'threatened margin' in rectal cancer.

Anaesthetic care:

This should be standardised in each centre irrespective of the randomisation.

Surgical procedure:

Surgery should be carried out in a standard fashion by the same surgeon, the only difference being the method of access. Rectal tumours within 10 cm of the anal verge should be treated by total mesorectal excision accompanied, whenever possible, by preservation of the hypogastric nerves. Tumours are defined as being rectal when at or within 15 cm of the anal verge on rigid sigmoidoscopy performed with the patient awake.

Quality control of surgery:

To enter the trial each surgeon must have performed more than 200 laparoscopic colorectal resections and more than 50 open total mesorectal excisions for rectal cancer. All surgeons will be provided with video recordings of standardised laparoscopic operative procedures, which have been prepared for the Laparoscopic Colorectal Preceptorship Programme. Macroscopic assessment of the quality of mesorectal dissection will be provided to each surgeon.

Postoperative chemotherapy or radiotherapy:

Postoperative chemotherapy or radiotherapy may be used but should be standardised irrespective of randomisation and treatment details recorded for each patient.

Outpatient follow up and investigations:

Patients should be seen at 2 weeks, 4 weeks, 3 months and 6 months following surgery.

Protocol for patient management including key features of the Enhanced Recovery Programme and criteria for discharge:

1. Before admission:

1.1. Conditioning of expectations: counselling with patient and carer. Provision of written information regarding pathway and discharge criteria. Meeting with stoma nurse if stoma anticipated. Identification of factors that might delay discharge and consideration of solutions, e.g., provision of support when discharged if living alone

1.2. Co-morbid risk assessment: optimised pre-morbid health status

2. Day before surgery:

2.1. Nutrition: three high protein/high calorie drinks

2.2. Bowel preparation: when oral preparation is used it should only be in patients undergoing total mesorectal excision and reconstruction

3. Day of surgery:

3.1. Bowel preparation: enema preoperatively for planned transanal stapled anastomosis

3.2. Anaesthesia: thoracic epidural with bupivacaine. Intraoperative fluid standardised and limited. Local anaesthetic infiltration to the largest wound in minimal access surgery

3.3. Surgery: no nasogastric tubes or surgical drains

3.4. Open surgery: small transverse or curved incisions when possible

4. Postoperative care:

4.1. Pain relief: continuous epidural analgesia for at least 48 hours. Regular paracetamol and non-steroidal-anti-inflammatory/equivalent

4.2. Fluids: high protein/high calorie drinks day of surgery (+ diet if tolerated). Stop intravenous fluids morning after surgery

4.3. Mobilisation: patient to sit out in chair for 2 hours on day of surgery, patient dressed and sat out thereafter for 8 hours per day, assisted daily mobilisation of 4 x 60 m walks

4.4. Remove urinary catheter day 1 for colon and day 1 - 3 for rectal resections

4.5. Laxative from day 1

5. Discharge:

5.1. Discharge: aim for discharge day 2 - 3 for colons and proximal rectums; day 5 when a stoma fashioned. Discharge Criteria: patients must be tolerating normal food, mobilising independently and be managed on oral analgesics to fulfil discharge criteria

5.2. Follow up: provision of hospital contact numbers to allow discussion of problems; expedited review on ward if problems within 2 weeks of surgery. Review in out patient clinic at two weeks post operation

## **Intervention Type**

Other

## **Phase**

Phase III

## **Primary outcome measure**

Post-operative fatigue assessment using the 20-item Multidimensional Fatigue Inventory (MFI-20) which will be completed prior to randomisation and sent by post at 4 weeks, 3 and 6 months following surgery.

## **Secondary outcome measures**

1. Postoperative hospital stay: counting the day of operation as zero
2. Complications: 30 day morbidity will be assessed by the Research Nurse using a standardised definition of complications by blinded review within the first week and outpatient review at 2 and 4 weeks. 30 day readmission and reoperation rates, along with 30 day and in-hospital mortality will also be recorded
3. Patient reported and functional outcomes: self-reported quality of life will be assessed using the 36-item Short Form questionnaire. Questionnaires will be completed before randomisation and then sent by post at 4 weeks, 3 and 6 months following surgery. Standardised objective Performance Indicators (SPIs) using a standard test of lower limb strength, balance and endurance that takes approximately 5 minutes to measure - at the same time intervals as Quality of Life
4. Cosmetic outcomes: in order to assess the impact of surgery on the appearance of the body and the patient's confidence, a body image questionnaire will be completed preoperatively and one year after operation. Cosmetic outcome will be assessed using a body image scale calculated from questionnaires
5. Health economics outcomes: a health resource questionnaire will be completed for all patients providing information about the use of healthcare post-operatively for 6 months. Data collected will include General Practitioner (GP) surgery visits, GP home visits, District Nurse visits, inpatient hotel costs (including re-admission and re-operation within 28 days and convalescent care), operating theatre costs, drug costs, outpatient visits, physiotherapy and occupational therapy, hospital transport and the use of the service provisions. In addition, EuroQol (EQ5D) questionnaires will be used at the defined follow up intervals. Questionnaires to be completed post-operatively and then sent by post at 2 weeks, 4 weeks, 3 months and 6 months after surgery

## **Overall study start date**

31/10/2007

## **Completion date**

30/06/2012

## **Eligibility**

### **Key inclusion criteria**

1. Diagnosis of colorectal cancer (any stage)
2. Suitable for elective resection following a planned admission
3. Greater than or equal to 18 years of age
4. Written informed consent given

### **Participant type(s)**

Patient

### **Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Not Specified

**Target number of participants**

266 patients recruited from 8 to 10 sites, with 133 in each arm.

**Key exclusion criteria**

1. Acute intestinal obstruction
2. Unplanned admission to hospital
3. Unsuitability for epidural insertion - determined pre-randomisation
4. Pregnant
5. Unsuitable for laparoscopic resection as conversion to open surgery is likely, e.g., fixed tumours or rectosigmoid cancers which have a 'threatened margin' (defined as tumour at or within 1 mm of the circumferential resection margin) on preoperative imaging
6. Previous complex laparotomies

**Date of first enrolment**

31/10/2007

**Date of final enrolment**

30/06/2012

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

EnROL Trial Office

Oxford

United Kingdom

OX3 7DQ

**Sponsor information****Organisation**

University of Oxford and North West London Hospitals NHS Trust (UK)

**Sponsor details**

University Offices  
Wellington Square  
Oxford  
England  
United Kingdom  
OX1 2JD  
+44 (0)1865 287950  
research.services@admin.ox.ac.uk

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.ox.ac.uk>

**ROR**

<https://ror.org/03h2bh287>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Cancer Research UK (UK) - Trial approved for funding in November 2006, grant start date: 1st April 2007

## 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?
<a href="#">Plain English results</a>				No	Yes
<a href="#">Protocol article</a>	protocol	16/05/2012		Yes	No
	results				

[Results article](#)

10/06/2014

Yes

No