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

Submission date
23/07/2007

Recruitment status
No longer recruiting

Registration date
30/08/2007

Overall study status
Completed

Last Edited
26/10/2018

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Contact information

Type(s)
Scientific

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Additional identifiers

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

Study type(s)
Treatment

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., privision 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(s)
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.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

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
United Kingdom

England

Study participating centre
EnROL Trial Office
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Sponsor information

Organisation
University of Oxford and North West London Hospitals NHS Trust (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

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	10/06/2014		Yes	No

Protocol article	protocol	16/05/2012		Yes	No
Plain English results				No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes