

# A randomised controlled trial of laparoscopic surgery for colorectal cancer

<b>Submission date</b> 06/04/2000	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/04/2000	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/10/2021	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**ClinicalTrials.gov (NCT)**  
NCT00003354

**Protocol serial number**  
G9328312

## Study information

**Scientific Title**

A randomised controlled trial of laparoscopic surgery for colorectal cancer

**Acronym**

CLASICC

**Study objectives**

To determine whether disease-free and overall survival from laparoscopic surgery for colorectal cancer is comparable to that of conventional surgery as assessed by conventional end-points of survival and surrogate end-points of pathological findings

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Colorectal cancer

**Interventions**

Laparoscopic surgery vs conventional surgery

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

1. Pathological endpoints (circumferential, longitudinal and high-tie mesenteric resection margins)
2. 30-day operative mortality
3. Disease-free survival, overall survival and local recurrence rates at 3 years
4. Local and distal recurrence rates, quality of life and cost effectiveness

**Key secondary outcome(s)**

1. Disease-free and overall survival at 5 years
2. Port-site and wound-site recurrence
3. Complication rates
4. Quality of life and cost effectiveness

5. Blood transfusion requirements
6. Loco-regional, anastomotic and distant metastases

**Completion date**

31/12/2009

## Eligibility

**Key inclusion criteria**

1. Clinical diagnosis of colorectal cancer (unless this occurs in the transverse colon)
2. Suitable for elective surgical resection by right hemicolectomy, left hemicolectomy, sigmoid colectomy, anterior resection or abdomino-perineal resection
3. Aged >18 years
4. Give written informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Not Specified

**Key exclusion criteria**

1. Adenocarcinoma of the transverse colon
2. Any contraindication to pneumoperitoneum
3. Acute intestinal obstruction
4. Malignancy within previous 5 years (except basal cell carcinoma, in situ carcinoma of cervix or prostate cancer)
5. Synchronous multiple adenocarcinomas
6. If female, be pregnant
7. Associated gastrointestinal disease that requires surgical intervention

**Date of first enrolment**

01/07/1996

**Date of final enrolment**

31/12/2009

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**  
**Academic Unit of Surgery**  
Leeds  
United Kingdom  
LS9 7TF

## Sponsor information

**Organisation**  
Medical Research Council (MRC) (UK)

## Funder(s)

**Funder type**  
Research council

**Funder Name**  
Medical Research Council (MRC) (UK)

**Alternative Name(s)**  
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan**  
Not provided at time of registration

**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="#">Results article</a>	3 year results	20/07/2007		Yes	No
<a href="#">Results article</a>	results	01/01/2010		Yes	No
<a href="#">Results article</a>	results	01/11/2010		Yes	No
<a href="#">Plain English results</a>			28/10/2021	No	Yes