A randomised controlled trial of laparoscopic surgery for colorectal cancer

Submission date	Recruitment status No longer recruiting	Prospectively registeredProtocol		
06/04/2000				
Registration date	Overall study status	Statistical analysis plan		
06/04/2000	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
28/10/2021	Cancer			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number NCT00003354

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Colorectal cancer

Interventions

Laparoscopic surgery vs conventional surgery

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 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

Secondary outcome measures

- 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

Overall study start date

01/07/1996

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

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

1000. Closed to recruitment - in follow-up

Kev 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

England

United Kingdom

Study participating centre Academic Unit of Surgery

Leeds United Kingdom LS9 7TF

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

20 Park Crescent London United Kingdom W1B 1AL +44 (0)20 7636 5422 clinical.trial@headoffice.mrc.ac.uk

Sponsor type

Research council

Website

http://www.mrc.ac.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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Results article	3 year results	20/07/2007		Yes	No
Results article	results	01/01/2010		Yes	No
Results article	results	01/11/2010		Yes	No
Plain English results			28/10/2021	No	Yes