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A randomised controlled trial of laparoscopic surgery for colorectal cancer

Submission date	Recruitment status	[_] Prospectively registered
06/04/2000	No longer recruiting	[_] Protocol
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

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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

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
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
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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