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The role of endoluminal stenting in the acute management of obstructing colorectal cancer

Submission date 14/05/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/06/2008	**Overall study status** Completed	
Last Edited 22/08/2022	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-relieving-a-blockage-caused-by-suspected-bowel-cancer-with-a-tube-inside-the-bowel

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
The role of endoluminal stenting in the acute management of obstructing colorectal cancer

Acronym
CReST

Study objectives
For patients presenting acutely with obstructing left-sided colorectal cancer will be randomised between emergency surgery or endoluminal stenting. The aim of the study is to determine if endoluminal stenting results in:
1. A reduced perioperative morbidity as assessed by the length of hospital stay
2. Reduced perioperative morbidity
3. Reduced stoma formation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxford Research Ethics Committee B, 22/10/2008, ref: 08/H0605/90

Primary study design
Interventional

Study design
Open multi-centre randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obstructing colorectal cancer

Interventions
An open randomised controlled trial where patients will be randomised between emergency surgery and endoluminal stenting. All patients will present in the acute setting and will be put forward for urgent decompression.

Patients will be randomised between:
1. Endoluminal stenting
2. Surgical decompression with or without resection of the primary tumour

Intervention Type
Procedure/Surgery

Primary outcome(s)
Current primary outcome measures as of 13/03/2017:
1. Length of hospital stay, measured using site-completed trial-specific Case Report Forms at discharge and 12-month follow-up
2. 30-day mortality, measured using mortality data from ONS (also included on CRFs) at 30 days

Previous primary outcome measures:
1. Length of hospital stay
2. 30-day mortality
3. Presence and duration of a stoma

Key secondary outcome(s)
Current secondary outcome measures as of 13/03/2017:
Data collection points were baseline (screening/randomisation/procedure); discharge; 6 weeks; every 3 months in first year; every 6 months to 3 years:
1. Presence and duration of stoma, measured using intraoperative and discharge Forms (emergency and elective surgery), annual follow up forms
2. Stenting completion and complication rates, measured using stent insertion and stent follow up forms, following stenting at day 7 and day 28 post-stenting and up to 12 months
3. Anastomosis rate, measured using intraoperative form and discharge form, following emergency and elective surgery up to 12 months and then annually
4. 6-month survival, measured using ONS mortality data (also collected on CRFs) at 6 months
5. Quality of life, measured using patient-completed EORTC QLQ C30, QLQ CR29 and EQ-5D at discharge, 3 months and 1 year
6. Proportion disease free at 3 years, measured using ONS Cancer Registry data (also collected on CRFs) at 3 years
7. Length of stay in HRU and ITU, measured using intraoperative and discharge forms following emergency and elective surgery, and discharge form following stenting
8. Perioperative morbidity, measured using intraoperative and discharge forms for emergency and elective surgery
9. Cost benefit analysis, assessed using discharge forms (for bed days)
10. Rate of adjuvant chemotherapy and adherence to chemotherapy protocol, measured using annual follow-up forms

Previous secondary outcome measures:
1. Stenting completion and complication rate (arm A only). Complications will be recorded between 24 hours and 7 days (early) and between 7 and 28 days (late).
2. Anastomosis rate, recorded during surgery
3. Quality of life, measured by the EQ-5D and the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire for Cancer patients C29 and C30 at 6 weeks after surgery, then every 3 months for the first year, and every 6 months thereafter until 3 years
4. Proportion recurrence-free at three years (attempted curative surgery group only)
5. Length of stay on intensive treatment unit (ITU) and high-dependency unit (HDU) at 30 days post-operation
6. Perioperative morbidity
7. Cost benefit analysis

Completion date
01/06/2018

Eligibility

Key inclusion criteria
1. Both male and female patients (no specific age limit)
2. Radiologically proven colonic obstruction of left colon/upper rectum presumed secondary to a carcinoma
3. Patient considered sufficiently fit for surgery if allocated

Healthy volunteers allowed
No

Age group
All

Sex
All

Total final enrolment
246

Key exclusion criteria
1. Patients with signs of peritonitis and/or perforation
2. Patients with right iliac fossa tenderness and features of incipient caecal perforation
3. Patients with obstruction in the rectum that may require neoadjuvant therapy (i.e. tumours in the mid or lower rectum)
4. Patients who are unfit for surgical treatments or refuse surgical treatment
5. Pregnant patients

Date of first enrolment
01/03/2009

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Bradford Royal Infirmary
Bradford
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BD9 6RJ

Study participating centre
Darent Valley Hospital
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United Kingdom
DA2 8DA

Study participating centre
Derby Hospitals NHS Foundation Trust
Derby
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DE22 3NE

Study participating centre
Derriford Hospital
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Gartnavel General Hospital
Glasgow
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G12 0YN

Study participating centre

Glasgow Royal Infirmary
Glasgow
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G4 0SF

Study participating centre
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Study participating centre
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Study participating centre
Raigmore Hospital
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Study participating centre

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RG1 5AN

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EX2 5DW

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M6 8HD

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DN15 7BH

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University Hospital Coventry & Warwickshire
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CV2 2DX

Study participating centre

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Study participating centre
University Hospital of North Tees
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Study participating centre
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Sponsor information

Organisation
University of Birmingham (UK)

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/08/2022	22/08/2022	Yes	No
Abstract results		20/05/2016	07/05/2021	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes