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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

Study website
http://www.crest.bham.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Study design
Open multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
15/07/2008

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

Participant type(s)
Mixed

Age group
All

Sex
Both

Target number of participants
Total recruited 246 (target was 400)

Total final enrolment

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
England

Northern Ireland

Scotland

United Kingdom

Wales

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

Study participating centre
Bradford Royal Infirmary
Bradford
United Kingdom
BD9 6RJ

Study participating centre

Darent Valley Hospital
Dartford
United Kingdom
DA2 8DA

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

Study participating centre
Derriford Hospital
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Gartnavel General Hospital
Glasgow
United Kingdom
G12 0YN

Study participating centre
Glasgow Royal Infirmary
Glasgow
United Kingdom
G4 0SF

Study participating centre
Imperial College Healthcare NHS Trust
London
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W2 1NY

Study participating centre

Ipswich Hospital
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IP4 5PD

Study participating centre
James Paget University Hospital
Norwich
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NR31 6LA

Study participating centre
John Radcliffe Hospital
Oxford
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OX3 9DU

Study participating centre
King's College Hospital
London
United Kingdom
SE5 9RS

Study participating centre
Manchester Royal Infirmary
Manchester
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M13 9WL

Study participating centre
Musgrove Park Hospital
Taunton
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TA1 5DA

Study participating centre

Nevill Hall Hospital
Abergavenny
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NP7 7EG

Study participating centre
North Bristol NHS Trust
Bristol
United Kingdom
BS10 5NB

Study participating centre
North Devon District Hospital
Barnstaple
United Kingdom
EX31 4JB

Study participating centre
Northern General Hospital
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United Kingdom
S5 7AU

Study participating centre
North West London Hospitals NHS Trust
London
United Kingdom
HA1 3UJ

Study participating centre
Princess of Wales Hospital
Bridgend
United Kingdom
CF31 1RQ

Study participating centre

Queen Elizabeth Hospital
Birmingham
United Kingdom
B15 2GW

Study participating centre
Queen’s Hospital
Romford
United Kingdom
RM7 0AG

Study participating centre
Queens Medical Centre
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Raigmore Hospital
Inverness
United Kingdom
IV2 3UJ

Study participating centre
Royal Berkshire Hospital
Reading
United Kingdom
RG1 5AN

Study participating centre
Royal Cornwall Hospital
Truro
United Kingdom
TR1 3LQ

Study participating centre

Royal Bolton Hospital
Bolton
United Kingdom
BL4 0JR

Study participating centre
Royal Devon and Exeter Hospital
Exeter
United Kingdom
EX2 5DW

Study participating centre
Russells Hall Hospital
Dudley
United Kingdom
DY1 2HQ

Study participating centre
Salford Royal Hospital
Salford
United Kingdom
M6 8HD

Study participating centre
Scarborough General Hospital
Scarborough
United Kingdom
YO12 6QL

Study participating centre
Scunthorpe General Hospital
Scunthorpe
United Kingdom
DN15 7BH

Study participating centre

St James's University Hospital
Leeds
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LS9 7TF

Study participating centre
The Mid Yorkshire Hospitals NHS Trust
Wakefield
United Kingdom
WF1 4DG

Study participating centre
Ulster Hospital
Belfast
United Kingdom
BT16 1RH

Study participating centre
University Hospital Coventry & Warwickshire
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United Kingdom
CV2 2DX

Study participating centre
University Hospital Of North Durham
Durham
United Kingdom
DH1 5TW

Study participating centre
University Hospital of North Tees
Stockton-on-Tees
United Kingdom
TS19 8PE

Study participating centre

University Hospitals of Leicester NHS Trust
Leicester
United Kingdom
LE3 9QP

Study participating centre
Western General Hospital
Edinburgh
United Kingdom
EH4 2XU

Study participating centre
Yeovil District Hospital
Yeovil
United Kingdom
BA21 4AT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Research and Enterprise Services
Edgbaston
Birmingham
England
United Kingdom
B15 2TT

Sponsor type
University/education

Website
http://www.bham.ac.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, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
01/04/2018

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?
Abstract results		20/05/2016	07/05/2021	No	No
Results article		20/08/2022	22/08/2022	Yes	No