ISRCTN54834267 https://doi.org/10.1186/ISRCTN54834267

The CReST2 Trial: Are uncovered or covered stents more effective in relieving bowel obstruction in people with colorectal cancer

Submission date
13/03/2017

Recruitment status
No longer recruiting

Registration date
20/03/2017

Overall study status
Completed

Last Edited
23/09/2025

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-different-types-of-stent-to-treat-bowel-obstruction-in-people-with-bowel-cancer

Contact information

Type(s)
Public

Contact name
Dr Laura Magill

Contact details
Birmingham Clinical Trials Unit
Institute of Applied Health Research
College of Medical and Dental Sciences
University of Birmingham
Birmingham
United Kingdom
B15 2TT
+44 121 415 9105
e.l.magill@bham.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 32120

Study information

Scientific Title
CReST2: Colorectal Stenting Trial 2: uncovered vs covered endoluminal stenting in the acute management of obstructing colorectal cancer in the palliative setting

Acronym
CReST2

Study objectives
The aim of this study is to assess whether covered stents used for palliative patients with obstructing colorectal cancer, will result in an improved Quality of Life when compared to uncovered stents.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/02/2017, North East - Tyne & Wear South Research Ethics Committee (HRA Jarrow, Rolling Mill Road, Jarrow, NE323DT, United Kingdom; +44 (0)2071048084; hra.studyregistration@nhs.net), ref: 17/NE/0027

Study design
Randomised; Interventional; Design type: Treatment, Device, Complex Intervention, Surgery

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Colorectal cancer

Interventions
The trial will compare covered with uncovered colonic stents. The trial is blinded and only the person inserting the stent will know the allocation. Randomisation will be provided by a secure online randomisation system at the coordinating centre (BCTU) and the allocation will be sent to the person inserting the stent.

The stents used in the trial are existing, commercially available products which are licensed and CE marked. Participating sites can use the stent of their choice. Stents will be inserted as a joint endoscopic/fluoroscopic procedure by individuals experienced in performing colonic stenting.

The target population are patients treated with palliative intent. Therefore, the stents will remain in-situ, unless there are complications requiring further interventions. Following stent insertion the site's standard care pathways will be followed and patients will be treated symptomatically.

Patients will be followed-up at their usual out-patient appointments and data collected for a total of 24 months.

Intervention Type
Other

Primary outcome(s)
1. Quality of Life is measured using the EORTC QLQ C30 at baseline and 3 months post-stenting (30 days for patients dying before 3 months)
2. Stent patency is measured using Stent Follow Up Form (completed by site) at 6 months post-stenting

Key secondary outcome(s))
Secondary outcome measures as of 01/10/2018:
1. Stenting success rate is measured by Stent Insertion Form (completed by site) at the time of stent insertion
2. Time to onset of stent related complications in the short term, intermediate term and long term is measured by Stent Follow Up Forms (completed by site) at 30 days post stenting, 1-3 months post stenting and 3-12 months post stenting
3. Stent related complication rates of patients on chemotherapy is measured by Stent Follow Up Form at 12 months
4. Cumulative frequency and duration of stoma formation is measured by Stent Follow Up Forms (as above), Intraoperative Form up to 12 months
5. Overall survival is measured by ONS data at 12 months. Stent Follow Up Forms record date of death (if applicable). However, we also obtain mortality data from ONS.
6. Cost effectiveness (cost per QALY) is measured by EQ-5D-5L; trial specific forms also collect some data which will be used to assess resource use
7. Quality of Life at 3 months measured using the QLQ-CR29 Disease Specific Module for Colorectal Cancer

Secondary outcome measures as of 12/01/2018:
1. Stenting success rate is measured by Stent Insertion Form (completed by site) at the time of stent insertion
2. Time to onset of stent related complications in the short term, intermediate term and long term is measured by Stent Follow Up Forms (completed by site) at 30 days post stenting, 1-3 months post stenting and 3-12 months post stenting
3. Stent related complication rates of patients on chemotherapy is measured by Stent Follow Up Form at 12 months
4. Cumulative frequency and duration of stoma formation is measured by Stent Follow Up Forms (as above), Intraoperative Form up to 12 months
5. Overall survival is measured by ONS data at 12 months. Stent Follow Up Forms record date of death (if applicable). However, we also obtain mortality data from ONS.
6. Cost effectiveness (cost per QALY) is measured by EQ-5D-5L; trial specific forms also collect some data which will be used to assess resource use

Previous secondary outcome measures:
1. Stenting success rate is measured by Stent Insertion Form (completed by site) at the time of stent insertion
2. Time to onset of stent related complications in the short term, intermediate term and long term is measured by Stent Follow Up Forms (completed by site) at 30 days post stenting, 1-3 months post stenting and 3-12 months post stenting
3. Stent related complication rates of patients on chemotherapy is measured by Stent Follow Up Form at 12 months
4. Cumulative frequency and duration of stoma formation is measured by Stent Follow Up Forms (as above), Intraoperative Form up to 12 months
5. Overall survival is measured by ONS data at 12 months. Stent Follow Up Forms record date of death (if applicable). However, we also obtain mortality data from ONS.
6. Cost effectiveness (cost per QALY) is measured by all trial specific forms collect some data to be used to assess resource use (i.e. Stent Insertion, Hospital Discharge Form, Follow Up Forms, Intraoperative Form) at 24 months

Completion date
30/04/2025

Eligibility

Key inclusion criteria
1. Patients aged 16 year and over
2. Patients presenting with obstructing colorectal cancer, which is to be treated with palliative intent
3. Patients able and willing to give written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
377

Key exclusion criteria
1. Patients with impending or established perforation of the colon
2. Patients with low rectal cancer, i.e. a carcinoma in the lower third of the rectum
3. Patients being treated or considered for treatment with antiangiogenic drugs (e.g. bevacizumab)
4. Pregnant patients

Date of first enrolment
16/06/2017

Date of final enrolment
30/04/2022

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Countess of Chester Hospital
Liverpool Road
Chester
United Kingdom
CH2 1UL

Study participating centre

Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Queens Hospital
Rom Valley Way
Romford
United Kingdom
RM7 0AG

Study participating centre
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Nevill Hall Hospital, Abergavenny
Brecon Road
Abergavenny
United Kingdom
NP7 7EG

Study participating centre
Blackpool Victoria Hospital
Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Study participating centre
University Hospitals Birmingham
Mindelsohn Way
Birmingham
United Kingdom
B15 2TH

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

Study participating centre
Basingstoke and North Hampshire Hospital
Aldermaston Road
Basingstoke
United Kingdom
RG24 9NA

Study participating centre
The Ulster Hospital
Upper Newtownards Road
Dundonald
Belfast
United Kingdom
BT16 1RH

Study participating centre
Musgrove Park Hospital, Taunton
Parkfield Drive
Taunton
United Kingdom
TA1 5DA

Study participating centre
Macclesfield District General Hospital
Victoria Road

Macclesfield
United Kingdom
SK10 3BL

Study participating centre
Raigmore Hospital, Inverness
Old Perth Road
Inverness
United Kingdom
IV2 3UJ

Study participating centre
Northern General Hospital
Herries Rd
Sheffield
United Kingdom
S5 7AU

Study participating centre
Royal Gwent Hospital
Cardiff Road
Newport
United Kingdom
NP20 2UB

Study participating centre
Wythenshawe Hospital
Southmoor Rd,
Wythenshawe
Manchester
United Kingdom
M23 9LT

Study participating centre
New Cross Hospital
Wolverhampton Rd,
Heath Town
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Royal Stoke Hospital
Newcastle Rd
Stoke-on-Trent
United Kingdom
ST4 6QG

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

Study participating centre
Royal Victoria Infirmary
Queen Victoria Rd
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
Royal Bolton Hospital
Minerva Rd,
Farnworth
Bolton
United Kingdom
BL4 0JR

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

Sponsor information

Organisation
Manchester University Hospitals NHS Foundation Trust

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

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		02/09/2025	23/09/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V1	19/12/2016	20/03/2017	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes