

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/03/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/01/2025	Condition category Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

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>

Study website

www.birmingham.ac.uk/CReST2

Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

See additional files

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 measure

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

Secondary outcome measures

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

Overall study start date

01/07/2016

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

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 350; UK Sample Size: 350

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

England

Northern Ireland

Scotland

United Kingdom

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

Sponsor details

Trust Headquarters
Cobbett House
Manchester Royal Infirmary
Oxford Road
Manchester
England
United Kingdom
M13 9WL

Sponsor type

Hospital/treatment centre

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

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 02/02/2022:
The timing of the first main analysis is three years after the final patient enters the study (approximately March 2023). The final paper will be submitted to a high-impact peer-reviewed journal.
The trial website is in available (www.birmingham.ac.uk/CReST2).
CReST2 is represented on the ACPGBI website (Association of Coloproctology of GB and Ireland).

Previous publication and dissemination plan:
The timing of the first main analysis is two years after the final patient enters the study (approximately January 2022). The final paper will be submitted to a high-impact peer reviewed journal.
A trial website is in preparation (www.birmingham.ac.uk/CReST2).
CReST2 is represented on the ACPGBI website (Association of Coloproctology of GB and Ireland).

Intention to publish date

31/03/2023

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?
Participant information sheet	version V1	19/12/2016	20/03/2017	No	Yes
HRA research summary			28/06/2023	No	No