CReST2

ColoRectal Stenting Trial 2

Uncovered vs covered endoluminal stenting in the acute management of obstructing colorectal cancer in the palliative setting.

INFORMATION FOR LOCAL PRINCIPAL INVESTIGATORS

*For new centres wishing to participate in the **CReST2** trial*

CReST2 is a blinded, multi-centre randomised controlled trial to determine whether covered or uncovered stents are most efficacious in improving the quality of life in patients with bowel obstruction arising from colorectal cancer.
The study is funded by NIHR HTA and is coordinated by the University of Birmingham Clinical Trials Unit (BCTU).
The CI for the study is Professor James Hill, Consultant General and Colorectal Surgeon, Central Manchester University Hospitals NHS Foundation Trust.

The lead local researcher for a multi-centre study is the local Principal Investigator.

The role of Local Principal Investigator carries certain responsibilities:

- Day-to-day responsibility for the conduct of the research
- Recruitment into the study at site
- Ensuring the Research Governance requirements for the centre & study are met
- Ensuring the agreed protocol is followed
- Helping health care professionals ensure participants receive appropriate care while involved in the research
- The integrity of records and ensuring they are kept confidential
- Reporting adverse reactions.

All sites require confirmation of capacity and capability from their Trust before the trial can commence at site.

- No patients can be approached for consent to join the study until this is in place
- The CReST2 Trial Office can assist in the approval process if this form is completed and returned to the CReST2 Trial Office (contact details on back page).
- There are no excess treatment costs for sites as both covered and uncovered stents are now recognised as standard care

Good Clinical Practice (GCP) Training

- The local PI and anyone assessing eligibility and taking informed consent should be GCP trained; a copy of the certificate should be held at site and will be requested by R&D and the CReST2 Trial Office
- BCTU strongly encourages all people working on trials to be GCP trained.

CReST2 is funded by the National Institute for Health Research's HTA programme

National Institute for Health Research

CReST2 Site Registration Form

For all centres wishing to participate in the **CReST2** trial
*Please complete all sections below and return to the **CReST2** Trial Office*

Principal Investigator

Name: _____

Position: _____

Qualifications: _____

Department: _____

Hospital: _____

Address: _____

Telephone: _____

Email: _____

Experience of the Local Principal Investigator

The CReST2 PI should be a consultant radiologist, consultant surgeon or consultant gastroenterologist

Has the proposed PI been a PI, or is a PI for any other trials? **YES / NO**
Please delete as applicable

Does the PI have current GCP training? **YES / NO**
Please delete as applicable

*If answered **NO**, the PI needs to undertake GCP training prior to participation in **CReST2***

When does the PI plan to undertake/renew GCP training? _____

Has the **CReST2** trial and its requirements been discussed locally with surgical and radiology colleagues.
Please delete as applicable

YES / NO

Number of patients expected to be recruited:

In the first year? _____

For the duration of the study?
(*recruitment period is 3 years)* _____

Experience of performing stents

Did your site participate in CReST? **YES / NO**

Please delete as applicable

How many colorectal stents has your centre performed in the last 3 years?

_____

Please provide names of any **members of the research team** who have performed 10 or more stents:

Name	Position

Which brand(s) of stent do you use?

_____

_____

When is there access to stenting at your site?
e.g. Monday to Friday 9am – 5pm; out of hours provision(please give details)

_____

_____

Which stent technique is used at your site?
Please insert the percentage for each technique.

Radiological alone ____ %

Combined radiological and endoscopic ____ %

Location for research

Please indicate where each of the following research activities will take place.

Research activity	Location
Consent	
CT Scan	
Other diagnostic procedure (please specify)	
Insertion of stent	
Follow up	
Other (please state)……	

Who will be responsible for obtaining consent at site?

*Anyone taking informed consent should be GCP trained; a copy of the certificate should be held and will be requested by R&D and the **CReST2** Trial Office*

Please note: Nurses can introduce and discuss the trial with patients. However, written, informed consent must be taken by a medically qualified person who has been delegated this task.

Name	Position

Who will be the main administrative contact at site

Please provide the contact details of the person who will deal with day-to-day administration of the trial at your site e.g. liaising with Trust R&D re approvals, maintenance of Investigator Site File, first point of contact at site.

Name: _____

Position: _____

Address _____

_____

Telephone: _____

Email: _____

Members of the research team

*Please list all staff that will be involved in the **CReST2** Trial, including surgeons, radiologists, gastroeneterologists, research nurses and local coordinators.*

Participating consultant surgeon (not PI):

Name: _____

Position: _____

Telephone: _____

Email: _____

Participating consultant radiologist (not PI):

Name: _____

Position: _____

Telephone: _____

Email: _____

Participating consultant gastroenetreologist (not PI):

Name: _____

Position: _____

Telephone: _____

Email: _____

Participating research nurse:

Name: _____

Position: _____

Telephone: _____

Email: _____

Participating other:

Name: _____

Position: _____

Telephone: _____

Email: _____

Participating other:

Name: _____

Position: _____

Telephone: _____

Email: _____

*Please see next page for **CReST2** contact details*

Thank you for the completing the CReST2 site registration form

*Please return to the **CReST2** Trial Office by e-mail, post or fax:*	
CReST2 Trial Office **Birmingham Clinical Trials Unit (BCTU)** **Institute of Applied Health Research** **College of Medical and Dental Sciences** **Public Health Building** **University of Birmingham** **Edgbaston** **Birmingham** **B15 2TT**	CreST2 Trial Manager Andy Palmer | a.palmer@bham.ac.uk CReST2 Team Lead Manjinder Kaur | m.kaur@bham.ac.uk **Tel: 0121 415 9965** **Fax: 0121 415 8871** **Crest2@trials.bham.ac.uk**

Please remember to include:

- **Signed and dated CVs for researchers**
- **GCP certificates when available**