The CReST Trial  
The ColoRectal Stent Trial

**Rationale**

Colorectal cancer is the second most common malignant disease in developed countries, with up to 30% presenting as an emergency with large bowel obstruction. Emergency surgery is associated with high morbidity and mortality, prolonged hospital stay and a high frequency of stoma formation. Stenting of these bowel obstructions provides the potential to avoid emergency surgery, allow full assessment and preparation of the patient for surgery with the potential to reduce operative morbidity and improve QoL and survival, although this procedure is not without its own risks. CReST is a RCT developed by the NCRI colorectal cancer Clinical Studies Group which aims to investigate whether endoluminal colonic stenting for obstructing CRC will result in reduced operative morbidity, reduced length of hospital stay, a reduced rate of stoma formation & improved QoL & survival compared to conventional treatment.

**CReST is now the biggest & only ongoing colorectal stent trial! In May 2012 the 150th patient was randomised!** The importance of CReST is highlighted by the early closure of the Dutch and French studies due to concerns about poor success rates and complications. The CReST DMEC have reviewed unblinded data & have no concerns about the CReST Trial.

**Trial Design**

**Objectives**

**Primary objective:**
To determine if endoluminal stenting for obstructing colonic cancer can result in:
- Reduced perioperative morbidity
- Reduced 30-day mortality

**Secondary objectives:**
To assess:
- Reduces stoma formation
- Improves quality of life
- Increases ability to tolerate adjuvant chemotherapy
- Has demonstrable benefits in the palliative & attempted curative settings
- Improves overall survival

CReST is a multi-centre phase III, RCT with a target recruitment of 400 patients. Recruitment is due to end in late 2013.

**Randomised Comparison**

Patients presenting acutely with left-sided colonic obstruction and radiological features consistent with a carcinoma who are considered to require urgent decompression are randomised to either:

A) Endoluminal stenting  
B) Surgical decompression with or without resection of the primary tumour

**Eligibility Criteria**

**Inclusion criteria:**
- Radiologically proven colonic obstruction of the left colon/upper rectum presumed secondary to a carcinoma  
- Patient considered sufficiently fit for surgery if allocated  
- Able to give written, informed consent

**Exclusion criteria:**
- Patients with signs of peritonitis &/or perforation  
- Right iliac fossa tenderness & features of incipient caecal perforation  
- Obstruction in mid or lower rectum which may require neoadjuvant chemo  
- Patients unfit for surgery or who refuse surgical treatment  
- Pregnant patients

**Outcome Measures**

**Primary outcome measures:**
- Length of hospital stay
- 30-day mortality

**Secondary outcome measures:**
- Presence & duration of a stoma
- Stenting completion & complication rate
- Anastomosis rate
- 6-month survival
- Quality of life
- Proportion disease-free at 3 years
- Length of stay on ITU & HDU
- Perioperative morbidity
- Resource usage
- Rate of adjuvant chemo & adherence to chosen chemotherapy protocol

**SAEs in CReST**

Within CReST, serious adverse events include, but are not limited to:

1. Failure to deploy stent  
2. Bowel perforation  
3. Stent displacement/reobstruction

SAEs should be reported to the CReST Study Office using the SAE form provided within 1 week of the site becoming aware of the event.
To find out more about the reduced rates that these companies offer please email www.crest.bham.ac.uk

They are:

- Pyramed
- Boston Scientific
- BVM Medical
- Cook Medical
- ConMed

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There are currently 5 approved stent suppliers for CReST who offer sites participating in the trial a reduced rate.

Open CReST Centres

There are now 48 UK centres open to recruitment to CReST, with a further 10 sites in set up. The trial is also open in South Africa & planned to open in Australia & Sweden. (Sites highlighted in green are those which have recruited patients into the trial.)