Enteric Healthcare Technology Co-operative

NHS National Institute for Health Research

Newsletter

SMART Trial Special Supplement

February 2014

SMART included in ESCP Portfolio

We are pleased to announce that the European Society of Coloproctology Research Committee has accepted SMART as part of their Pan European Trial Portfolio Map. The Research Committee compiles a portfolio of clinical trials that can be made available for international collaboration across the EU. The ESCP initiative provides a grant (£400/ €500) to support the translation of study protocols and their submission to the ethical committees. This is a great opportunity for other European investigators to join SMART. For further information about this ESCP initiative, visit www.escp.eu.com.

Hospital de Sagunto Valencia, Spain

New SMART Trial Sites

The SMART trial continues to take Europe by storm. We are pleased to announce that the trial has expanded in Germany and Spain.

Dr Matthias Berger is leading the team at the Klinikum Chemnitz in Chemnitz, Germany and Hospital de Sagunto in Valencia, Spain is lead by Dr Roberto Lozoya Trujilo.

We are in the process of acquiring other European and UK sites. We look forward to our new sites joining in early 2014.

Klinikum Chemnitz, Germany

SMART PROCEDURE

A cylinder of skin and subcutaneous tissue is excised. The anterior rectus sheath is opened, the muscle split and gently retracted. At open surgery, the posterior sheath/peritoneum is pierced with the tips of an artery forceps that grasp the anvil shaft of a Compact™ (Chex™ CS Compact, Frankenman International Ltd, Hong Kong) Circular Stapling gun (28 mm) placed within the abdominal cavity (Fig. 1). The anvil shaft is withdrawn through the posterior rectus sheath and exteriorised. The fully extended trocar of the gun, pre-loaded with a circular configured mesh (Vipro II™, Ethicon),13 cm in diameter is mated with the exteriorised anvil shaft (Fig. 2). The gun is closed, fired and removed, encompassing a disc of mesh, posterior rectus sheath and peritoneum and leaving a precise reinforced stapled trephine (Fig. 3). The outer mesh circumference is sutured to the anterior rectus sheath so it lines the trephine. The stoma is fashioned in the usual way (Fig. 4).

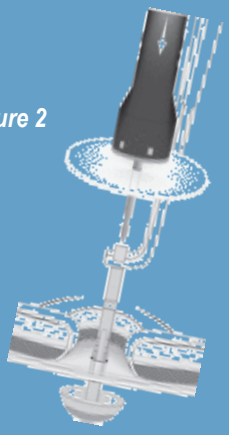
When performed laparoscopically, an incision is made in the posterior rectus sheath/ peritoneum and a purse string suture placed in its edge. The anvil head is inserted through the incision, the purse string tied, pneumoperitoneum is re-established and the anvil shaft is mated with the spike of the gun.

Williams N.S, Nair R, & Bhan, C. Stapled mesh stoma reinforcement technique (SMART) - a procedure to prevent parastomal herniation. Ann R Coll Surg Engl. 2011 March; 93(2): 169.

Figure 1

The shaft of the anvil is delivered through the posterior rectus sheath and mated with the trocar of the circular stapling device preloaded with mesh.

Figure 2

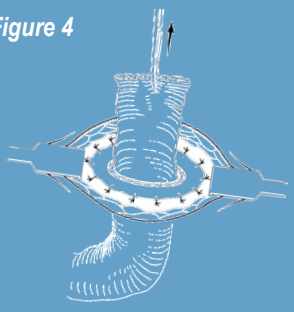


The circular stapling device is closed and fired.

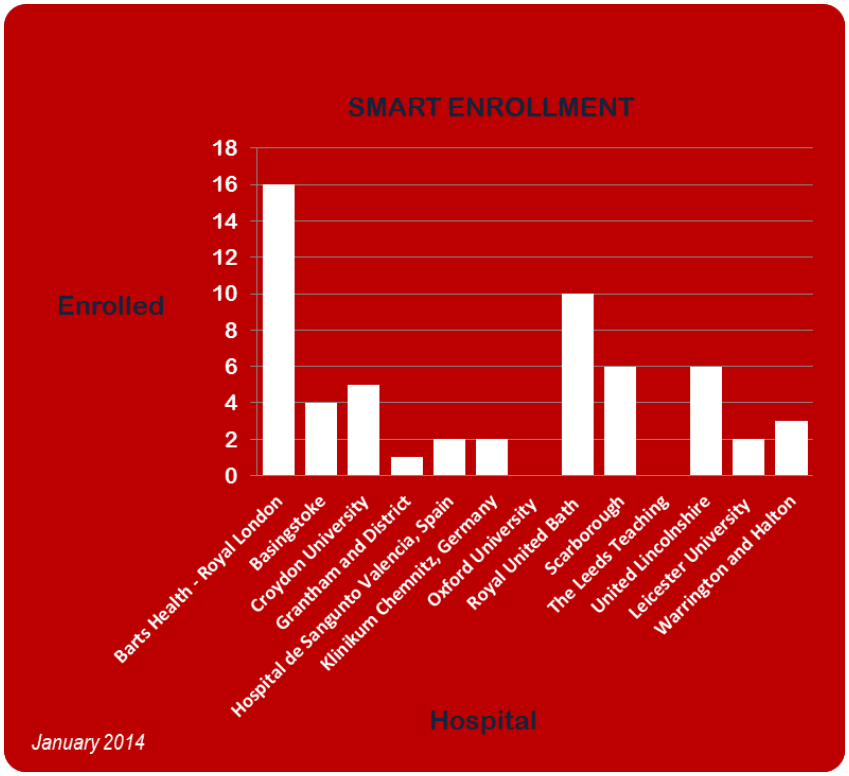
Figure 3

Once the circular stapling device has been removed, a mesh reinforced trephine is left behind. The edges of the mesh are then sutured to the anterior rectus sheath.

Figure 4



The colon or ileum is exteriorised through the trephine and the stoma is fashioned in the usual way.



2014 Rings in New Recruitment

It's a balancing act to manage clinical roles with research projects. We would like to acknowledge and thank all of our trial sites for their recruitment efforts.

Our key goal for 2014 is to complete the enrollment phase of SMART. If you need any support or have any queries, please contact Sybil Bannister at s.bannister@qmul.ac.uk or (+44)(0) 2078 828 753 or Alex Hotouras at alex007@doctors.org.uk.

Recruitment Bites: PIISS Principles

Recruitment is probably one of the most challenging aspects of conducting a clinical trial. Lack of enrollment in a trial may not record sufficient events to show benefit of a intervention. On the other hand, lack of recruitment leads to clinical site closures – wasted resources.

Some investigators are now contemplating the use of technological solutions to aid in recruitment efforts. These novel solutions may be effective in increasing enrollment but tend to be expensive. Before allocating part of the research budget on technological solutions, investigators should ensure the trial recruitment plan has incorporated the basic **PIISS** principles.

Developing a recruitment **P**lan is the key to successful enrollment. When formulating the research plan, review patient trends to calculate realistic enrollment targets. Do not forget to calculate seasonal variation for referrals or clinic list.

Develop a local criteria for recruiting a cohort of patients in competitive studies.

Regular trial specific meetings are essential in successful recruitment. The trial meeting is the perfect setting to apply the Who, What, and When approach to delegation of recruitment tasks. The trial meeting is where study related risks are reviewed, particularly the recruitment strategy, and offers an opportunity to mitigate those risks.

Increase awareness of the clinical trial by informing colleagues and patient's support groups of eligibility criteria. Update these key stakeholders regularly on the trial progress - this keeps the trial in the spot light and provides another route for recruitment.

Incorporating research screening as part of the integrated clinical pathway. This means that patients are **S**creened from referrals and clinic lists. Many researcher find conducting paper research rounds with clinic colleagues to be beneficial in their recruitment efforts.

Finally, **S**election of a participant is not a passive process. Whether you first introduce the patient to the clinical trial during a clinic visit or by sending out the patient information

Clinical Trial Site

- **Prof Norman Williams**
  Mr Christopher Chan
  Mr Alex Hotouras
  The Royal London Barts Health NHS Trust
- **Mr Mike Williams**
  Royal United Hospital Bath NHS Trust
- **Mr Richard Guy**
  Oxford University Hospital
- **Mr Muti Abulafi**
  Croydon University Hospital
- **Mr A. Venkatsubramaniam**
  Basingstoke Hospital NHS
- **Mr Dermot Burke**
  The Leeds Teaching Hospitals NHS Trust
- **Mr Mike Norwood**
  University of Leicester NHS Trust
- **Mr Antony Barlow**
  Mr Suresh Pillai
  Miss Aarti Varma
  United Lincolnshire Hospital NHS Trust
- **Mr Serban Gheorghlu**
  Scarborough NHS Trust
- **Mr Barry Taylor**
  Warrington and Halton NHS Foundation Trust
- **Mr Pasquale Giordano**
  Whipps Cross University Hospital NHS Trust
- **Dr Matthias Berger**
  Klinikum Chemnitz Chemnitz, Germany
- **Dr Roberto Lozoya Trujilo**
  Hospital de Sagunto Valencia, Spain

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NIHR Enteric HTC

About Us

We are one of eight national Healthcare Technology Co-operatives funded by the National Institute for Health Research the NIHR Enteric HTC at Barts Health NHS Trust aims to be the premier centre for facilitating innovative technology in bowel and gastrointestinal disorders for the NHS and beyond.

We are based in the National Centre for Bowel Research and Surgical Innovation (NCBRSI) and are building on the
success of the pilot HTC, enteric.

Contact us

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Email: info@enteric.org.uk
www.enteric.htc.nihr.ac.uk

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London E1 2AT

NIHR Enteric HTC Core Team

Clinical Co-Directors:

Professor Norman Williams
Professor Charles Knowles

Director of Technology:
Dr Michael Grahn

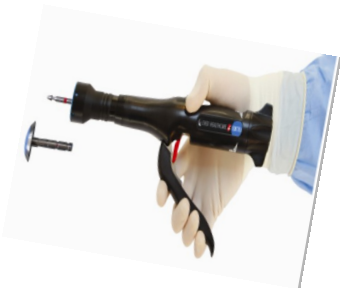
Business Development Manager:
Antonio Quadrucci

Administrator:
Sue Taylor

sheet in the post, it is essential to always follow up that contact. Following-up contacts provide the opportunity for the investigator to discuss the trial more in-depth with the patient and allow the patient's queries to be addressed.

PIIS is easy to apply, low tech and an inexpensive solution to patient recruitment.

Queen Mary University London's SMART TEAM



Professor Norman Williams is the Chief Investigator for SMART and developer of the Circular Stapler used in SMART. Prof William is also the Director of the National Centre for Bowel Research and Surgical Innovation and the President of the Royal College of Surgeons. He is a consultant to Frankenman International Ltd who have a licensing agreement with QMUL his employer.

Sybil Bannister is the newly appointed Research Nurse for SMART. Sybil jointed the team in October.

Sybil will be working with Mr Hotouras in the management of SMART data and operations.

If you have any SMART queries, please contact : s.bannister@qmul.ac.uk or (+44) (0) 207 882 8753

Mr Christopher Chan is a Co-Investigator for SMART. Mr Chan is a Senior Lecturer Consultant General and Colorectal Surgeon. His research interests include: Pelvic floor dysfunction, colorectal cancer, Cohn's disease and intestinal fistula

Mr Alex Hotouras is the Principle Investigator and the SMART Trial Manager at The Royal London. He is currently a Surgical Registrar and his research interest includes neuromodulation, pelvic floor dysfunction and parastomal hernia.