

# Colorectal Cancer Trials Newsletter (FOxTROT, CReST, Quasar Tumour Marker) December 2007



*Merry Christmas from BCTU and welcome to the CRC Trials newsletter.*

Welcome to the first issue of the Colorectal Cancer Trials newsletter from Birmingham Clinical Trials Unit. The colorectal trials coordinated by BCTU are **FOxTROT**, **CReST** and the **Quasar Tumour Marker study**.

We would like to thank all those who have participated in the Quasar Tumour Marker study, everyone participating in FOxTROT and all those who have agreed to participate in the upcoming CReST trial. We hope that everyone will continue to contribute towards future improvements in outcome for patients with colorectal cancer. The success of all of our trials depends on the wholehearted support of all of our collaborators, so thank you!

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- FOxTROT trial update
- The recently funded CReST trial
- Quasar TM study update



## ***The FOxTROT Trial is open to recruitment & is currently being launched around the country!***

FOxTROT is the first prospective randomised trial of neo-adjuvant therapy and targeted therapy for patients with operable colon cancer.

We are now having a number of launch meetings for the FOxTROT trial. So far there have been two very successful launches; one at Good Hope, Birmingham on 6th November and the second in Taunton on 7th December.

There are another 3 meetings scheduled, they are:

London	15th Jan, RMH
Leeds	16th Jan, Weetwood Hall
Wales	Feb 2008, location to be confirmed

At each meeting there will be a short presentation by each of the trial chief investigators followed by a discussion and then an opportunity to talk about the trial with researchers from other participating centres.

If you would like to attend any of the meetings or want further information on any meeting then please contact the FOxTROT study office on:

0121 415 9013 or e-mail [FOxTROTtrial@adf.bham.ac.uk](mailto:FOxTROTtrial@adf.bham.ac.uk)

## FOxTROT



FOxTROT has been developed by the NCRI Colorectal Cancer Surgical Subgroup and is funded by Cancer Research UK, MREC and MHRA approvals have been secured and the local ethics and R&D approvals are in place or pending for most centres.



### The primary objectives of the FOxTROT trial are:

- To determine if neoadjuvant chemotherapy+/- panitumumab followed by deferred surgery and completion of chemotherapy post-operatively can reduce 2-year recurrence as compared to surgery and postoperative chemotherapy +/- panitumumab.
- To determine if adding panitumumab in the neoadjuvant treatment produces a measurable

### Update on the progress of FOxTROT:

- ◇ MHRA and MREC approvals have been granted
- ◇ LREC and R&D approvals are being applied for
- ◇ Over 50 centres have signed up to participate



### The centres that have confirmed their participation in the FOxTROT trial are:

Confirmed Centres	Local PI	Confirmed Centres	Local PI
1 <i>Airedale General Hospital</i>	<i>C Raja Kapadia</i>	29 <i>LeedsTeaching hospitals NHS Trust</i>	<i>Matt Seynour</i>
2 <i>Birmingham Heartlands Hospital</i>	<i>Charles Hendrickse</i>	30 <i>St Mark's Hospital</i>	<i>David Burling</i>
3 <i>Bristol Royal Infirmary</i>	<i>Michael G Thomas</i>	31 <i>Velindre Cancer Centre</i>	<i>Richard Adams</i>
4 <i>Castle Hill Hospital /Hull Royal Infirmary</i>	<i>John Monson</i>	32 <i>Mount Vernon Hospital</i>	<i>Rob Glynne-Jones</i>
5 <i>Derriford Hospital</i>	<i>Clare Adams</i>	33 <i>New Cross</i>	<i>Simon Grumett</i>
6 <i>Dorset County Hospital</i>	<i>Richard Osborne</i>	34 <i>University Hospital of North Staffordshire</i>	<i>Fawzi Adab</i>
7 <i>Good Hope Hospital</i>	<i>John Glaholm</i>	35 <i>Derbyshire Royal Infirmary</i>	<i>Prabir Chakraborti</i>
8 <i>Huddersfield Royal Infirmary</i>	<i>Jo Dent</i>	36 <i>Queens Hospital - Burton</i>	<i>Prabir Chakraborti</i>
9 <i>Llandough Hospital</i>	<i>Richard Adams</i>	37 <i>University College London Hospital</i>	<i>John Bridgewater</i>
10 <i>Maidstone DGH</i>	<i>Mark Hill</i>	38 <i>North Middlesex Hospital</i>	<i>John Bridgewater</i>
11 <i>Manchester Royal Infirmary</i>	<i>Jim Hill</i>	39 <i>Princess Alexandra Hospital</i>	<i>John Bridgewater</i>
11 <i>Manor Hospital</i>	<i>Andrew hartley</i>	40 <i>Sandwell Hospital</i>	<i>Neil Cruickshank</i>
12 <i>Mayday University Hospital</i>	<i>Nigel Scott</i>	41 <i>Harrogate District Hospital</i>	<i>Kim Last</i>
13 <i>Royal Lancaster Hospital</i>	<i>David Eaton</i>	42 <i>Heatherwood and Wexham Park</i>	<i>Marcia Hall</i>
14 <i>North Hampshire Hospital</i>	<i>Brendan Moran</i>	43 <i>Clatterbridge Centre for Oncology</i>	<i>David Smith</i>
15 <i>Northern Centre for Cancer Treatment</i>	<i>Fareeda Coxon</i>	44 <i>Weston Park (Sheffield)</i>	<i>D Furniss</i>
16 <i>Poole General Hospital</i>	<i>Tamas hickish</i>	45 <i>Doncaster (Sheffield)</i>	<i>J Wadesley</i>
17 <i>Queen Alexandra Hospital</i>	<i>Daniel O'Leary</i>	46 <i>Yeovil District</i>	<i>Stephen Falk</i>
18 <i>Queen Elizabeth Hospital Birmingham</i>	<i>Neil Steven</i>	47 <i>Royal Marsden (London)</i>	<i>David Cunningham</i>
19 <i>Queen Elizabeth Hospital (Gateshead)</i>	<i>Bill Cunliffe</i>	48 <i>Royal Marsden (Surrey)</i>	<i>David Cunningham</i>
20 <i>Queens Medical Centre</i>	<i>Vanessa Potter</i>	49 <i>Cheltenham General</i>	<i>Dr Shepherd</i>
21 <i>Royal Cornwall Hospital (Treliske)</i>	<i>Will Faux</i>	50 <i>Hereford County</i>	<i>Nick Reed</i>
22 <i>Royal Free Hospital</i>	<i>O Ogunbiyi</i>	51 <i>Worcester Royal</i>	<i>David Farrugia</i>
23 <i>The Royal Glamorgan Hospital</i>	<i>Richard Adams</i>	52 <i>Charing Cross</i>	<i>C.P Lowdell</i>
24 <i>The Royal Liverpool University Hospital</i>	<i>Paul Rooney</i>	53 <i>Scunthorpe General Hospital</i>	<i>Abdel Hamid</i>
25 <i>Russells Hall</i>	<i>David Ferry</i>		
26 <i>Royal Surrey County Hospital</i>	<i>Christopher Marks</i>		
28 <i>Southampton General Hospital</i>	<i>Andrew Bateman</i>		

If your site is not listed here and your centre would like to participate then please contact the trial coordinator, Laura Magill, on 0121 415 9105 or e-mail at: [e.l.magill@bham.ac.uk](mailto:e.l.magill@bham.ac.uk)



## FOxTROT

**Radiology Training Days** A prerequisite to a site recruiting patients into FOxTROT is that the radiologist must have attended one of our CPD-accredited radiology training days. So far we have had 2 training days and a 3rd is scheduled for the 31st January. If you would like to attend on the 31st or you want to be kept informed of upcoming training days then please contact the FOxTROT Study office.

### Randomisation for FOxTROT

Once your centre has LREC and R&D approval in place, the FOxTROT study office will arrange for Panitumumab to be delivered to your pharmacy. At this time you will also receive your FOxTROT site file. You will not be able to randomise a patient until your site has full approval.

To randomise a patient call:

**0800 953 024**

Please ensure that you have answered all of the questions on the randomisation notepad before calling



Please look us up on the FOxTROT website:

[www.FOxTROT.bham.ac.uk](http://www.FOxTROT.bham.ac.uk)



### The CReST trial has just been funded by a grant from CRUK!

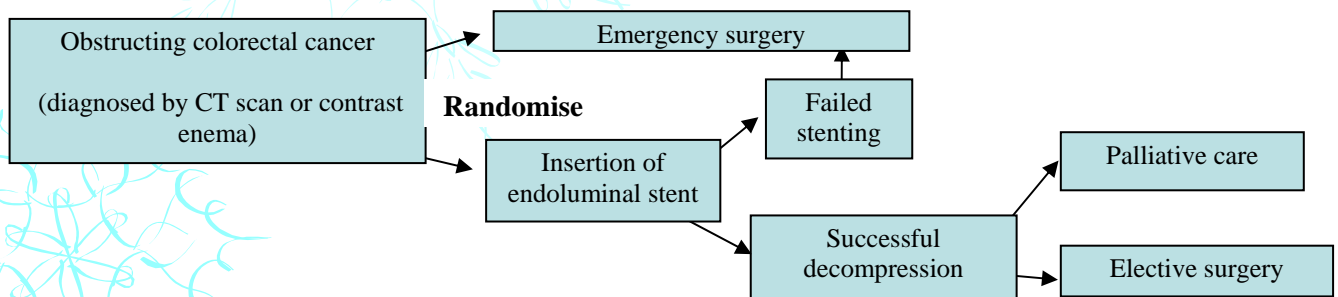
CReST - The Role of endoluminal stenting in the acute management of obstructing colorectal cancer.

CReST aims to recruit 400 patients over 3 years, over 30 centres have already confirmed that they are interested in participation in the trial. If you would like to participate please contact the Colorectal trials team at BCTU.

The Chief Investigator of the CReST trial is Mr Jim Hill.

CReST has been developed by the NCRI Colorectal Cancer Surgical Subgroup and designed to assess whether endoluminal stenting for obstructing colon cancer compared to primary emergency surgery reduces:

- ◇ Operative morbidity
- ◇ Duration of hospital stay
- ◇ Need for a stoma
- ◇ &/or improves quality of life and survival



## QUASAR Tumour Marker Study

Paraffin-embedded tissue blocks were stored at the time of surgery from almost all patients entered into the **QUASAR** study. This tissue represents an invaluable resource as **QUASAR** comprises by far the largest group of patients in the world with stage II colorectal cancer randomised to receive either a course of adjuvant chemotherapy or to observation alone. The distinction between prognostic and predictive variables can only be made by study of randomised cohorts such as **QUASAR**. Thus, we have a unique opportunity to investigate whether the efficacy of chemotherapy varies by demographic variables (e.g. age, sex), by pathological characteristics (tumour site and size, vascular invasion, lymphocytic infiltrate, mucin, infiltrative growth pattern) and/ or by genetic markers (e.g. thymidylate synthase, p53, dUTPase, cox-2, mgmt, msh-2, mlh-1, DNA ploidy).

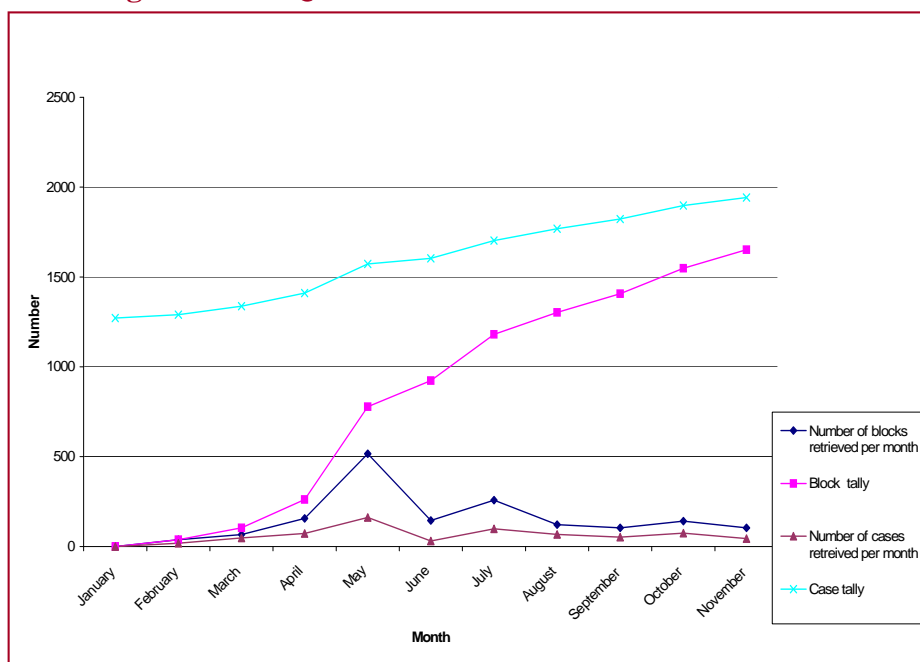
### The aim of the Quasar Tumour Marker study - why you should participate!

We are trying to build a tissue bank of FFPE tissue blocks and pathology reports from as many as possible of the 3239 patients in the uncertain indication randomisation arm of the **QUASAR** trial.

So far we have collected blocks from over 1940 patients; this has allowed preliminary investigations of the *prognostic* value of different pathological and genetic markers. However, we need to collect blocks from many more **QUASAR** patients for adequate statistical power to investigate variables *predictive* of sensitivity to chemotherapy.

We can only accomplish this if all pathologists involved in **QUASAR** help us to locate these tissue blocks.

### The Progress of the QUASAR Block Collection.



Thank you to everyone who has contributed to the **QUASAR Tumour Marker Study!** The graph on the left shows the significant progress we have made with the retrospective collection of FFPE– tissue blocks from patients entered into **QUASAR**, but we need your continued help to collect as many tissue blocks as possible!



### The QUASAR Tumour Marker Study—how you can help:

By now you will have been contacted by the **QUASAR** Tumour Marker study coordinator, Dr Laura Magill. You will have been provided with a list of patients randomised from your site into the uncertain indication arm of the **QUASAR** trial. We ask that you return a block of normal tissue and a block of tumour tissue along with the corresponding pathology report. For each set of patient blocks and pathology report returned we will provide £100 to cover admin costs.

### CONTACT INFORMATION:

For information on sending blocks, or if you have not received your patient lists, please contact the Colorectal trials office:

[QUASARtrial@adf.bham.ac.uk](mailto:QUASARtrial@adf.bham.ac.uk)

Tel: 0121 415 9105

