

**MINUTES OF THE 19th MEETING OF
ANGLO CELTIC COOPERATIVE ONCOLOGY GROUP
INTENSIVE CHEMOTHERAPY FOR HIGH RISK BREAST CANCER**

Friday 9th May 2003

PRESENT:

Dr J Crown

Prof RCF Leonard

Co-Chair

Co - Chair

Dr J Bartlett
Dr D Cameron
Dr P Canney
Prof R Coleman
Dr S Dean
Dr H Earl
Dr M Morishto
Dr P Neven
Dr R O'Connor
Dr G Thomas
Dr M Verrill
Dr A Wardley
Dr E Whipp
Dr A Yellowlees

Glasgow Royal
Edinburgh
Glasgow (Beatson)
Sheffield
Poole
Cambridge
Swansea
Leuven, Belgium
Dublin
Swansea
Newcastle
Christie, Manchester
Bristol
Quantics

Amant Frederic
Ingrid Keywerts
Daisy Supply
Ellen Mertens
Inge Lefever

Leuven
Leuven
Leuven
Leuven
Leuven

Dr L Foster
Dr A Gould
Mr M Hiemann

SCTN Edinburgh
SCTN Edinburgh
SCTN Edinburgh

Nancy Dams
Nadia Delens
Gabriel Fox
Dr L Hamilton
Erik Janssen
Tom Lillie
Siobhan Nolan
Ms M Pluck
Denise Richard
Kathleen Segers
Muriel Sterckx

Lilly
Roche
Co Medica Ltd
Astra Zeneca
Aventis
Amgen
Lilly UK
Aventis UK
Aventis UK
Pharmacia
BMS Belgium

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Friday 9th May 2003, Leuven, Belgium

	ACTION
<p>1. Apologies. RL conveyed apologies to the meeting. A list of these may be obtained, if required, from LF.</p>	LF
<p>2. Minutes of the last meeting, and Matters Arising The minutes of the last meeting were adopted.</p>	
<p>3. Pharmaceutical Company Support RL thanked all the Pharmaceutical Companies who were involved in supporting the Group. A discussion “in camera” would be held at the end of the meeting</p>	
<p>4.OPTION and ACCENT Ovarian Protection Trial In Oestrogen Non-responsive Premenopausal breast Cancer Patients Receiving Adjuvant or Neo-adjuvant Chemotherapy. Option has been re-submitted to CTAAC. Zoladex would be used. 400 patients required. Bone studies will be carried out. ACCENT – benefits of chemotherapy in elderly patients. Design still to be finalised.</p>	
<p>5. Neo-Adjuvant Trial New design explained by Helena Earl based on TANGO (same regimens) and will run in parallel with TANGO. Requires 800 patients with 200 fresh bio-samples for translational research. Rob Coleman questioned whether patients would be disadvantaged if on single agent taxol and if there was a case for a small Phase II trial first. The main trial would be run from the Birmingham Trials Unit. Dave Cameron asked the Group to support p53 until Helena’s study is up and running. DC will ask for NCRN badging for p53. Protocols were requested by PN, GT and JB.</p>	LF
<p>6. TACT II Bearing in mind the NEAT and McNEAT data, it was proposed to have</p>	

<p>an Epi/CMF control arm. A questionnaire has been sent out on a proposed 2X2 design. ? accelerated Epi with GCSF support. ? replace CMF with capecitabine. ? duration. Hoping to go to CTAAC in June and would need 4000 patients. PN noted that Leuven use FEC rather than Epi/CMF. Is it possible to incorporate this. DC will follow this up.</p>	<p>DC</p>
<p>7. SOFEA Faslodex downregulates oestrogen receptor. There is some data that Faslodex is active post Arimidex. Compare Faslodex to Exemestane. 3 arm trial – Faslodex, Exemestane, Faslodex + Arimidex. 750 patient needed, launch meeting in May. Sub-studies will be done.</p>	
<p>8. AZURE Professor Rob Coleman had been invited to present AZURE to the Group. Does Adjuvant Zoledronic acid Reduce Recurrence in patients with high risk localised breast cancer. This is an adjuvant bisphosphonate trial supported by Novartis and using Zoledronate. Hoping to recruit 3300 patients over 3 years. Randomisation will use a minimisation technique and the trial will be coordinated by Yorkshire with some of the collaborative groups. £750 per patient payment and free drug. The trial has gone for NCRN adoption.</p>	
<p>9. Biological Sub Studies. John Bartlett reported from the substudies group. The website would be used for displaying a pro forma for using material collected from Anglo Celtic studies. www.Angloceltic.org.uk JB explained how blocks would be collected through SCTN and TMA's made in Glasgow. Requests for using the material should be made through the Bio substudy group to avoid duplication and loss of samples.</p>	
<p>10. A 1st line Metastatic trial John Crown, Dave Cameron, Rob Coleman, Mark Verrill, John Bartlett and Bob Leonard would be in contact as a writing committee for a 1st line metastatic trial. LF to email them all with an outline of taxotere trial.</p>	<p>LF</p>
<p>11. WHETHER This is a proposed trial in HER2 negative breast cancer. A summary of the trial had been sent out to all investigators and Bob Leonard would like comments. Comments already received will be passed to RL by LF.</p>	<p>LF</p>
<p>12. ACCOG II Ann Yellowlees reported on this trial. All pathology reports have now been received and baseline results analysed. Complete or Partial CR is not significant between the 2 arms. 80% of patients had surgery. Complete path response - no difference between the 2 arms. Ann also reported on toxicity. Survival data showed AT slightly better but not significant – VERY EARLY to report. An abstract will go to San</p>	

Antonio.	
<p>13. Will Weekly Win Now reached 10% of proposed recruitment. Would all participants please remember the blood collection, a simple 10ml EDTA sample.</p>	
<p>14. SPROG After discussions with Amgen about Neulasta (new form of GCSF requiring a single shot one day after chemo), RL will put an amendment to MREC and give investigators the opportunity to use either form of GCSF. This trial has now been adopted by NCRN.</p> <p>LF had sent out a query about taking part in a European – wide Neutropenia Audit. 500 euro per patient payment. LF will resend this as some investigators had not received this email. All comments received so far will be forwarded to RL</p>	<p>RL</p> <p>LF</p>
<p>15. BCIRG trial JC reported on a BCIRG trial Node +ve and HER –ve. TAC x 6 vs AC x 4 – Tax x 4 vs Tax x 4 – AC x 4 Contact JC if interested. JC also reported on the EBDIS trial. 110 patients looking at event free survival for the highdose arm. Results +ve and statistically significant. The trial was double transplant and very little induction chemo.</p>	
<p>16. Pharmaceutical support. This discussion was held without Pharma reps. The Group agreed that RL should go ahead and meet with AZ representatives with a view to holding a Translational Educational Meeting as an extra Anglo celtic meeting towards the end of the year. The Group will discuss this in October.</p>	RL
<p>17. Next Meeting. Dr Patrick Neven was thanked for the meeting held in Leuven and congratulated on the success of the meeting. Professor Rob Coleman offered to host the next meeting in Sheffield on October 3rd 2003.</p>	RC, LF