

**MINUTES OF THE 25th MEETING OF
ANGLO CELTIC COOPERATIVE ONCOLOGY GROUP
INTENSIVE CHEMOTHERAPY FOR HIGH RISK BREAST CANCER**
Friday 3rd November 2006

PRESENT:

Prof RCF Leonard
Prof J Crown
Prof P Neven
Dr J Mansi

Co-Chair
Co-Chair
Leuven
St Georges

Prof G Thomas
Dr Nick Murray
Dr Mark Verrill
Prof John Bartlett
Prof Alistair Thompson
Suzanne Robinson
Gill Bruce
Leanne Ferrigan
Michelle McLinden
Victoria Knox

Cardiff
Southampton
Newcastle
Edinburgh
Dundee
Sanofi Aventis
Lilly
SCTN
SCTN
ACCOG Co-ordinator

Chris Gallagher

London/Barts

APOLOGIES:

Alison Humphreys, Ann Yellowlees, Mary Quigley, Rob Stein, Dr Alison Jones, Dr Perren, Douglas Adamson, Max Mano, Dr Ellis, Peter Canney, Sarah Reynia (Amgen), Julia Nicolson (Roche)

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ACTION

A rather small turnout, but important people were there with a good debate especially concerning future trial designs.

Welcome / Impact of EBCTCG 2006 on ACCOG trials: Prof R Leonard

Prof Leonard introduced the meeting with a brief resume of the status of our current trials

Anglo Celtic VIII (CARAT) study: Dr J Mansi

Dr Mansi reviewed the status of this post primary chemotherapy trial. There is little enthusiasm for a chemotherapy intervention after surgery but there may be a possibility of gaining support from Industry for an anti angiogenesis agent intervention. Dr Mansi and Dr Gallagher will progress this.

ACTION Update (especially HER2+VE subgroup study)

WHETHER Trial: Prof R Leonard

Professor Leonard presented the final version of this over-70's trial to be launched on Nov 30th. There is still uncertainty as to what to do over the issue of HER2 positive disease. Discussions are underway with Roche over Herceptin intervention but a Lapatinib study is an alternative option.

He also presented an outline of a taxotere first line trial that would precede the WHETHER intervention trial. However, the general feeling was that metastatic studies with taxanes or taxane combinations would not gain much support from investigators.

An alternative option would be to link WHETHER question to CARAT as both populations represent patients with minimal or non-detectable disease but with a very high risk of relapse. For both an antiangiogenic agent study might make sense.

Dr Mansi will lead this [as above]

ACCOG 8 Trial?: Dr Mark Verrill

Dr Verrill proposed a new trial for HER2+VE breast cancer to minimise cardiac damage from Herceptin. The idea is to test the hypothesis that prophylactic **angiotensin** converting enzyme (ACE) inhibitors can be used to reduce the frequency of cardiac events leading to treatment discontinuation in patients receiving adjuvant Trastuzumab as part of the adjuvant treatment of early breast cancer.

The ACE inhibitor Ramipril (Tritace, Sanofi-Aventis) is licensed for the prophylaxis of heart failure secondary to myocardial infarction. The hypothesis of this trial is that a similar benefit might accrue to patients receiving Trastuzumab, reducing or eliminating the need for cardiac

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monitoring and increasing the number of patients who complete Trastuzumab treatment.

Use of ACE inhibitors may also allow patients with borderline cardiac function to be treated safely with Trastuzumab

Patients with HER-2 positive early breast cancer who have received adjuvant chemotherapy will be selected for the trial. LVEF should be measured at baseline and must be >50%. Randomisation will be to Ramipril or placebo for the duration of Trastuzumab (usually 1 year). Cardiac function monitoring will continue as normal with 3 monthly assessments for the year of adjuvant Trastuzumab treatment.

Anglo-Celtic Marker Study in Metastatic Breast Cancer: Dr N Murray

Nick Murray reviewed his proposals for a marker-directed study of metastatic breast cancer.

The trial would compare standard treatment against marker-directed treatment.

Trial size would need a minimum of 1500 patients.

He has applied for funding from the HTA and outcome is not yet known.

Review of Translational Studies

Discussion of Proposed Biological Sub Studies for ACTION: Prof G Thomas

Gerry Thomas outlined a number of substudies in progress or planned for the existing ACCOG trials. The pathway for consent for substudies planned for the ACTION trial was discussed. A TRICC application will be made to provide funds for collection of biomaterials. The lead in each centre will be approached to provide contact details for the pathologists in each centre where tissue may be collected. Where centres have established tissue banks, approaches for material would be made via these banks. The slides from the presentation are attached.

NEXT MEETING: 27th April 2007, Edinburgh