

## **NCRI Testis Cancer Clinical Studies Group**

2005/6 has been successful year for the Testis CSG with the publication/presentation of a number key papers during the year. This includes the results of TE19 protocol which has established carboplatin as a major treatment option in stage I Seminoma, a range of papers from the Group's genetics protocol, the results of the Group's last adjuvant chemotherapy trials in stage I NSGCT and the outcome of the the Group's study of TIP in relapsed disease. In addition the results of two of the Group's studies (TE08 and TE22 protocols) were presented orally at ASCO and interim results of a further study (TER2) was presented as a poster.

During 2005/6 the Group continued to pursue its agreed strategy of:

1. Understanding the biological basis of testis cancer with a strong emphasis on the translational research as a component of clinical trials.
2. Improved surveillance and diagnostic imaging in order to detect and manage disease relapse earlier.
3. Improving outcome of poor prognosis groups.
4. Examination of the issues of long-term toxicity following treatment, including how to best manage this aspect and develop new treatment strategies to minimise these risks without jeopardising improved outcomes.

### **Portfolio and accrual**

As a step to meet these goals a protocol of salvage chemotherapy in relapse germ cell tumours commenced [GEM-TIP lead by Dr. Ben Mead] and a local study looking to detect late relapse in NSGCT [Chief Investigator Dr Robert Huddart] was adopted by the Group. A meeting to discuss studies in stage I disease was hosted by the group in July 2005. This has resulted in the development of a study of imaging and follow up in stage I Seminoma (Chief Investigator Dr Johnathan Joffe) which is currently undergoing funding review and agreement to participate in a collaborative study of adjuvant chemotherapy in stage I NSGCT which is at a developmental stage. A proposal to expand the groups' familial genetics protocol is also under funding review. The Group plans to work with EORTC to undertake more detailed quality of life analysis of previous trial data. Accrual was 5.9% of incident cases.

### **Membership**

After major changes in membership last year the membership has remained stable with the reappointment of the chair for a further 3 years commencing from November 2005, and Dr Joffe from February 2006 for 2 years.

### **Strategy**

The strategy of the Group over the next 3 years is:

1. Completion of recruitment to currently open therapy protocols
2. Progression and to commencement of phase III trial in poor prognosis disease following completion of CBOP BEP randomised phase II.
3. Development and opening during 2007 of surveillance trial in stage I seminoma and adjuvant chemotherapy in stage I NSGCT
4. Development of salvage chemotherapy protocol to follow form GEM TIP and investigatory studies in refractory disease during 2007-8.
5. Opening and Recruitment to over 2006 -2008 of national testis collection for familial association studies
6. Development of protocols to investigate treatment late effects over 2006-7
7. Collaborative studies investigating Qol in testis cancer patients after treatment.

## Publications

Publications 2005-6

Dearnaley DP, Fossa SD, Kaye SB, et al .Adjuvant bleomycin, vincristine and cisplatin (BOP) for high-risk stage I non-seminomatous germ cell tumours: a prospective trial (MRC TE17). *Br J Cancer*. 2005 Jun 20;92(12):2107-13.

Oliver R, Mason MD, Mead GM, et al. Radiotherapy versus single dose carboplatin in adjuvant treatment of stage I seminoma: a randomised trial. *Lancet* 2005;366(9482):293-300

Mead GM et al . A phase II trial of TIP (paclitaxel, ifosfamide and cisplatin) given as second-line (post-BEP) salvage chemotherapy for patients with metastatic germ cell cancer: a medical research council trial. *Br J Cancer*. 2005 Jul 25;93(2):178-84.

Nathanson KL et al The Y Deletion gr/gr and Susceptibility to Testicular Germ Cell Tumour *Am J. Hum.* 2005 *Genet* 77:1034-1043

Crockford GP et al. Genome-wide linkage screen for testicular germ cell tumour susceptibility loci. *Human Molecular Genetics* 2006 Jan Vol. 15, No. 3: 443-451

## Key Abstracts

Harland et al The familial influence on bilateral testicular germ cell cancer: Medical Research Council study TER2 Proc ASCO abstract 4590

Mead et al Medical Research Council Trial of 2 versus 5 CT scans in the surveillance of patients with stage 1 non-seminomatous germ cell tumours of the testis. Proc ASCO abstract 4519

Huddart et al A prospective study of 18FDG PET in the prediction of relapse in patients with high risk clinical stage 1 (CS1) non seminomatous germ cell tumour (NSGCT) MRC study TE22. Proc ASCO abstract 4520

## Testis Cancer Group Portfolio

Acronym	Title	PI(s)	Status
Accelerated BEP	Accelerated BEP chemotherapy for intermediate and high risk metastatic germ cell tumour.	Dr Michael V Williams	Open
BEP Continuous Infusional Bleomycin - TE3	A randomised Phase II Toxicity Study of Day 2,8,15 Short (30 Minute) Versus Day 1,2,3 Long (72 Hours) Infusion Bleomycin for Patients with IGCCCG Good Prognosis Germ Cell Tumours, TE3	Dr Jonathan Shamash	Open
Familial TGCT	Identification and molecular analyses of families with susceptibility to Testicular Germ Cell Tumour Cancer	Dr Robert Huddart	Open
Gem-TIP	Phase I/II multicentre trial of salvage chemotherapy with Gem-TIP for relapsed germ cell cancer	Dr Ben Mead	Open
TE08	A randomised Trial of Two CT Scans Versus Five CT Scans in the Surveillance of Patients with Stage I Teratoma of the Testis	Professor Gordon Rustin	Closed

TE21	A phase II/III randomised trial of BEP vs paclitaxel-BEP in intermediate risk metastatic germ cell tumours. (EORTC 30983)	Ms Sally Stenning, Dr M Sokal	Open
TE22	A study of 18-FDG PET in the prediction of relapse in patients with a clinical stage I non-seminomatous germ cell tumour	Dr Robert Huddart	Closed
TE23	Randomised Phase II trial of intensive induction chemotherapy (CBOP/BEP) and standard BEP chemotherapy in poor prognosis male germ cell tumours	Dr Robert Huddart	Open
TER2	Risk of testis cancer in the families of patients with bilateral testicular germ cell malignancy	Dr Stephen Harland	Closed
TIP	A phase II study of paclitaxel, cisplatin and ifosfamide as induction therapy in the treatment of patients relapsing after BEP (bleomycin, etoposide, cisplatin) chemotherapy for patients with metastatic germ cell tumours.	Professor Malcolm Mason, Dr Ben Mead	Closed
Late CT study	Assessment of the utility of CT follow up in the long term follow up of patients with metastatic non seminomatous germ cell tumour (NSGCT)	Dr Robert Huddart	Open

Dr Robert A. Huddart, Chair

## Appendix 1: Key strengths and issues from the Progress Review, April 2005

### Strengths:

- The Group were praised on their Familial Testicular Germ Cell Tumour Study, which is a good example of international collaboration
- The Group are open, well connected with the wider community and are making every effort to be more inclusive and collaborative
- The Group are developing a number of new trials in order to cover all stages of the disease and to increase accrual.

### The Group needs to consider:

- Broadening membership to include a pathologist and a testis scientist
- Seeking greater involvement of young clinicians in the Group
- Obtaining greater input from specialists with interests in genetics, QoL, health services research, health economists and translational studies, either through full membership or input at appropriate times
- Reflecting on how best to engage more fully with the wider research community, particularly the "silent community" who are not involved in developing new studies in partnership with the Group
- Collaborating internationally on trials for intermediate and poor prognosis groups
- Securing funding for a surveillance study possibly through resubmitting to CTAAC an amended version of the PASST study (surveillance strategies for stage I testicular germ cell cancer)
- Linking up with the Breast and Colorectal Clinical Studies Groups to discuss how best to develop follow-up studies
- Linking with fellow international chairs in order to improve scientific research
- Proactively approaching networks with poor accrual
- Discussing with the Director of the NCTR how best to collect testicular tissue and establish a tissue bank
- Extending work with the pharmaceutical industry