

Welcome to the first issue of the Australia and New Zealand Melanoma Trials Group (ANZMTG) newsletter. The ANZMTG executive committee and staff have been busy and 2008 has been a year of significant growth and development for the group.

The ANZMTG executive committee comprises 5 members, there are 4 ANZMTG staff members (Executive Officer, Biostatistician, Senior Project Officer and Research Assistant) and group membership is currently 138.

Since the 2007 Clinical Oncological Society of Australia (COSA) Annual Scientific Meeting, the ANZMTG membership has increased by 100%. There is growing interest in melanoma clinical trials and the ANZMTG offers a research network for supporting and developing large-scale, multi-centre studies which would be difficult for any single centre to complete. The group's effective infrastructure as a result of funding support from Cancer Australia has allowed us to expand our trial portfolio; this now includes 4 current clinical trials and 3 proposed trials.

ANZMTG Clinical Trials Update

Current	Study Status	Sites
ANZMTG 01/07: Whole Brain Radiotherapy following local treatment of intracranial metastases of melanoma - a randomised phase III trial (in collaboration with TROG, SNOG & NHMRC CTC)	Approved, initiation pending	ANZ sites = 10
ANZMTG 01/02: A randomised clinical trial of surgery versus surgery plus adjuvant radiotherapy for regional control in patients with completely resected macroscopic nodal metastatic melanoma (in collaboration with TROG)	Recruitment closed / Follow up	ANZ sites = 16 ANZ pts = 222 randomised
Multicenter Selective Lymphadenectomy Trial II (MSLT-II) (in collaboration with the John Wayne Cancer Institute)	Open - Recruiting	ANZ sites = 5 ANZ pts = 764 screened, 153 randomised
Multicenter Selective Lymphadenectomy Trial I (MSLT-I) (in collaboration with the John Wayne Cancer Institute)	Recruitment closed / Follow up	ANZ sites = 3 ANZ pts = 1033 randomised

Proposed	Protocol Status
Vitamin D versus placebo in resected stage IIc and IIIb melanoma	In development
RTN2 - A randomised trial of post-operative radiation therapy following wide excision of neurotropic melanoma of the head and neck (in collaboration with TROG & NHMRC CTC)	In development
Surgery versus surgery with systemic immunotherapy with BCG (bacille Calmette-Guerin) versus best medical therapy	In development

Clinical Trials Overview

1. ANZMTG 01/07

Whole Brain Radiotherapy following local treatment of intracranial metastases of melanoma - a randomised phase III trial

This study is investigating the efficacy in controlling distant intracranial disease and survival benefit of whole brain radiotherapy (WBRT) in patients after local treatment of intracranial metastases of melanoma. The trial will also investigate neurocognitive function and quality of life during the course of treatment. The role of WBRT post local treatment is controversial and there is variation in WBRT practice (nationally and internationally) but there have been no randomised clinical trials to date. This study will provide the groundwork for establishing the best evidence based practice for WBRT in melanoma.

We have been working hard to finalise the protocol and study documents and anticipate the study will open in September 2008. Updates to follow!

Related links: www.anzctr.org.au (trial no. ACTRN12607000512426), www.anzmtg.org

ANZMTG "Hollywood" Moment - Neurocognitive Function Assessment Training DVD

In February 2008, the ANZMTG with the assistance of Ms Haryana Dhillon (School of Psychology, University of Sydney) and Wicked Groove Pty Ltd filmed and produced a DVD – "Neurocognitive Function Assessment Training". The purpose of the DVD is to train the site Co-ordinators and Investigators to administer the neurocognitive function testing in a standardised manner. The training tools (DVD, script and checklist) have already been distributed to WBRT sites. Site staff have been invited to attend face-to-face training at the ANZMTG offices in August 2008.

2. ANZMTG 01/02

A randomised clinical trial of surgery versus surgery plus adjuvant radiotherapy for regional control in patients with completely resected macroscopic nodal metastatic melanoma

Surgical excision is the standard treatment for relapsed regional disease and many of these patients will achieve long-term control. Patients with a significant disease burden in the regional lymph nodes have a high rate of local recurrence. There is still a lack of reliable markers to predict nodal recurrence after complete nodal dissection with or without adjuvant radiation therapy. The response of melanoma to radiation is variable and is not fully explained by standard clinical or histological factors. Uncontrolled regional disease after failed surgery is a debilitating condition which is frequently impossible to manage satisfactorily. It has long been held that adjuvant radiotherapy after surgical excision will reduce the risk of regional recurrence.

Objective: To test the hypothesis that there is a difference in regional relapse rates for patients undergoing complete surgical resection of macroscopic nodal metastatic melanoma alone compared with patients receiving complete surgical resection followed by adjuvant radiotherapy.

Related links: www.anzctr.org.au (trial no. ACTRN12607000063415), www.anzmtg.org

3. Multicenter Selective Lymphadenectomy Trial II (MSLT-II)

This study is evaluating the efficacy and survival benefit of sentinel lymphadenectomy, followed by complete lymph node dissection in patients with evidence of sentinel node metastases compared to sentinel node biopsy and follow-up with ultrasound observation.

New data indicate that by using histopathological and molecular techniques, approximately 70-80% of melanoma patients with micrometastases in the sentinel nodes (SNs) have no other involved nodes. A complete lymph node dissection (CLND) may not be necessary in these patients because sentinel lymphadenectomy (SL) may have already removed all the nodes containing tumor metastases. This study investigates what is the best practice.

Objective: To determine whether lymphatic mapping / sentinel lymphadenectomy and complete lymph node dissection of the primary melanoma in those who are sentinel node positive will prolong overall survival compared to lymphatic mapping / sentinel lymphadenectomy alone.

Related links: www.anzctr.org.au (trial no. ACTRN12606000347561)

4. Multicenter Selective Lymphadenectomy Trial I (MSLT-I)

The hypothesis being tested in this study is that there is an improvement in overall and disease-free survival of patients treated with routine selective lymph node dissection if they are found to be sentinel node positive. Recruitment has closed and the survival / follow up data collection for this study continues.

Generally, it is accepted that regional lymphadenectomy is indicated for the patient with clinically suspicious or pathologically proven metastases to the regional lymph nodes. A major controversy, however, exists over whether early lymph node dissection in patients with clinically negative lymph nodes offers any therapeutic advantage over observation and later dissection when the patient has developed clinically obvious nodal metastases by which time many patients already have distant subclinical, micrometastatic disease which eventually leads to their death, despite lymphadenectomy. In contrast, most large series show that patients undergoing regional lymphadenectomy for identifiable microscopic lymph node metastases have improved survival rates.

Objective: To determine whether wide excision of the primary melanoma with intraoperative lymphatic mapping followed by selective lymphadenectomy in those who are sentinel node positive will prolong overall survival compared to wide excision of the primary melanoma alone.

Related links: www.clinicaltrials.gov (trial no. NCT00275496), www.anzmtg.org

ANZMTG extends support to Australian sites involved in MSLT-I & II studies

The ANZMTG has decided to assist Australian sites involved in these studies and will contribute a subsidy to each site. This support will assist sites in continuing to collect data for MSLT-I (up to and beyond 10 year follow up) and getting the MSLT-II study up and running at all sites.

Provectus PV-10 Chemoablation Study

Provectus Pharmaceuticals, Inc has begun recruiting patients for its Phase II clinical trial of their proprietary drug PV-10 as a therapy for metastatic melanoma. The current sites are Sydney Melanoma Unit (SMU) with clinics at the Royal Prince Alfred Hospital and Eden Street (John Thompson, PI), and Princess Alexandra Hospital in Brisbane (Mark Smithers, PI). To date these sites have enrolled 25 patients. Additional sites to join the study in the next several months are Royal Adelaide Hospital (Brendon Coventry, PI) and MD Anderson Cancer Centre in Houston Texas USA (Merrick Ross, PI). The total anticipated accrual is 80 patients, with 55 from Australian sites.

Study details are available at www.clinicaltrials.gov (trial no. NCT00521053)

Recent News: Provectus Fellowship Sponsorship

Provectus Pharmaceuticals, Inc and ANZMTG have combined forces to advance cutting edge melanoma research at the University of Sydney. On the 13th of June 2008, Provectus provided funding for an ANZMTG Research Fellowship position. The sponsorship of a Research Fellow has enabled the ANZMTG to engage a senior biostatistician (Associate Professor Julie Winstanley) who will design and analyse clinical trials for new treatments in melanoma and provides a model for future partnerships in this area. This is a great step forward in enhancing the personnel infrastructure & capacity of the group, which will provide benefits for future melanoma research in Australia and New Zealand and to patients and researchers worldwide.

From left: Dr Eric Wachter, Provectus Executive Vice President presents a cheque to Prof John Thompson, ANZMTG chair and Sydney Melanoma Unit Executive Director and Rachael Morton, ANZMTG Executive Officer



For full details and media releases visit: www.pvct.com, www.anzmtg.org and "[University of Sydney press release](#)"

Who is who in the ANZMTG?

The Executive Committee



Prof John Thompson (Chair)



Rachael Morton (Executive Officer)



A/Prof Michael Henderson



A/Prof John Kelly



Dr Benjamin Brady

Eshwini Tadiyal

Eshwini Tadiyal commenced as a Research Assistant at ANZMTG in March 2008. Eshwini is responsible for implementing strategies to enhance ANZMTG membership and inter-group collaboration both at national and international levels. She is also responsible for general housekeeping activities for ANZMTG including website administration, maintenance of ANZMTG specific databases, trial updates, and conducting surveys. Her current project involves research into Human Research Quality of Life instruments (HRQoL) specific to melanoma and the possible development of a melanoma QoL module.

Eshwini's professional interests include the provision of relevant, effective ANZMTG services to members and collaborative groups, appropriate use of technologies to enhance information-finding experiences, as well as staff and organisational development.

Libby Paton

In April 2008, Libby Paton commenced employment as the Senior Project Officer. Libby is responsible for developing quality assurance procedures for data monitoring, auditing of the trials and managing research grants. She is also initiating the ANZMTG consumer participation activities.

Libby has worked in different clinical research roles in Australia and Europe on a wide range of therapies. She enjoys working with the ANZMTG team and is excited to be involved during this formative period.

Julie Winstanley

Julie will commence her role as a senior Research Fellow (biostatistics) in September 2008. The ANZMTG is delighted with her appointment and extend a warm welcome and wish her every success in this role. Her position has been made possible by the ANZMTG with the support of Provectus Pharmaceuticals, Inc.

2008 Australia and New Zealand launch of the "Clinical Practice Guidelines for the Management of Melanoma in Australia and New Zealand"

"The Clinical Practice Guidelines for the Management of Melanoma in Australia and New Zealand" have been submitted to the NHMRC (Australia) and the New Zealand Guidelines Group for endorsement. The Guidelines will be launched in Australia during the COSA ASM (18th - 20th November 2008) and in New Zealand in conjunction with the national Melanoma Summit in Wellington (13th and 14th November 2008).

Australian and New Zealand melanoma experts have been meeting regularly through the year to review and discuss the content of the guidelines. The guidelines define best practice recommendations for the optimal treatment for patients with melanoma. The guidelines are expected to provide a best practice resource for doctors, health care professionals and patients.

Membership

The ANZMTG offers free memberships. Application can be completed online at www.anzmtg.org or by mail on request. By becoming a member to the ANZMTG members gain:

- Access to a professional network for researchers interested in melanoma research (including clinicians, nursing staff, industry affiliates and patient / consumer representatives)
- Support for the development of investigator-initiated studies
- Access to grant opportunities

Coming soon – A member survey on your expectations from ANZMTG

We are currently designing an on-line questionnaire for ANZMTG members. The aim is to target and identify the current priority areas for our members and to ensure that ANZMTG is continuing to expand the services and functions it offers and that it is contributing in a meaningful way to melanoma research. All members will be invited to participate in this survey. This is a great way of getting actively involved as an ANZMTG member and having your say, so please look out for the survey announcement!

Upcoming Event – The COSA ASM

COSA will hold its Annual Scientific Meeting from the 18th - 20th November 2008 in Sydney at the Sydney Convention Centre. This year there will be a focus on melanoma and non-melanocytic skin cancers. The ANZMTG will be holding a forum on Wednesday the 19th November 2008 and everyone is invited to attend.

Important Notice:

ANZMTG is offering limited travel grants to members to attend the 2008 COSA ASM, so if you need assistance to attend the meeting please contact us ASAP by email anzmtg@usyd.edu.au to obtain a grant application form.

ANZMTG Consumer Group

An important component of the ANZMTG structure is the inclusion, active involvement and participation of consumer representatives. Fundamental to the success of implementing clinical trials programs is consultation with these community members.

The ANZMTG is currently establishing a consumer group with the initial goal of consulting patients and carers with regard to clinical trials processes, patient information and informed consent processes and the effect of treatment of melanoma on quality of life. We are interested in speaking to any consumers (people affected by melanoma, patient or carer) who would like to be involved in this group. ANZMTG is committed to support and mentor consumers in their role. Currently, we are in the process of developing a number of resources and initiatives that will assist consumers become active and informed representatives in the development of clinical trials.

If you are interested or know someone who would be please contact Libby Paton, Senior Project Officer on +61 2 9911 7354 or email elizabeth.paton@smu.org.au



2008 Calender of Meetings (National and International)

Date	Name of Meeting	Place	Secretariat
September			
10 - 12	14 th Congress of the European Society of Surgical Oncology (ESSO)	The Hague Netherlands	ESSO c/o ECCO Brussels, Belgium Tel: +32 2 775 0246 Fax: +32 2 775 0200 Email: ESSO2008@ecco-org.eu Web: www.ecco-org.au
12 - 16	33 rd European Society for Medical Oncology (ESMO) Congress	Stockholm Sweden	ESMO Viganello-Lugano, Switzerland Tel: +41 91 9733 1919 Fax: +41 91 973 1918 Email: congress@esmo.org Web: www.esmo.org/activities/esmocongress/stockholm08
25 - 28	The Fourth Annual Oncology Congress	San Francisco USA	Web: www.oncologycongress.com
October			
2 - 4	Perspectives in Melanoma XII	Scheveningen / The Hague The Netherlands	Imedex Alpharetta, USA Tel.: +1 770 751 7332 Fax: +1 770 751 7334 Email: meetings@imedex.com Web: www.imedex.com
5 - 9	50 th American Society for Therapeutic Radiology and Oncology (ASTRO) Annual Meeting	Baltimore USA	ASTRO Fairfax, USA Tel: +1 703 502 1550 Fax: +1 703 502 7852 Email : meetings@astro.org Web : www.astro.org
November			
14	2008 Melanoma Summit	Wellington New Zealand	Health Sponsorship Council (HSC) Wellington, New Zealand Tel: +64 4 472 5777 Fax +64 4 472 5799 Email: susie@hsc.org.nz Web: www.hsc.org.nz/melanomasummit
18 -20	COSA Annual Scientific Meeting	Sydney Australia	Clinical Oncological Society of Australia – International Association of Cancer Registries Sydney, Australia Email: cosa@cancer.org.au Web: www.cosa-iacr.org
20 - 23	Second Worldwide Meeting of Melanoma Centres	Florida USA	More information will be made available on www.anzmtg.org in the coming months.

Farewell from Rachael Morton

It is with much sadness that as of the end of July 2008, I will be stepping down from my role as Executive Officer of the ANZMTG. Over the last four years I have seen the group grow immensely, obtaining significant grant funding, holding its first scientific seminar, developing new clinical trial protocols, supporting sites and employing research staff. I wish to thank the current ANZMTG Executive Committee for their commitment to the group; COSA and the Executive Officers Network for the opportunity to share ideas and resources; and Cancer Australia for its generous support. The ANZMTG is well placed to become the central hub of melanoma trials in this part of the world and has much to offer to new investigators and melanoma consumers. I wish the group all the best for the future and intend to stay in touch through the Executive Committee.

Message from Prof John Thompson

The remarkable progress made in establishing the ANZMTG, setting up and staffing has been largely due to the hard work and enthusiasm of Rachael Morton. She will be sadly missed as she leaves to take up a full-time research position in the Department of Public Health at the University of Sydney. We thank her for her contributions and wish her well in her future activities.

ANZMTG gratefully acknowledges the financial support from Cancer Australia. ANZMTG also acknowledges the assistance of: COSA, members of the ANZMTG Executive panel and staff for their continued support for ANZMTG trials and activities.

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